

US3442031 (Prod: Benchmark Research - Fort Worth)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:43:19

All time stamps listed in this document are displayed in GMT

US3442031

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

[Participant ID](#)

US3442031

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

US3442031

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:14:07

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Date of Informed Consent (<i>dd MMM yyyy</i>)	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:14:07

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:14:07

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 00:14:07

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Condition	THROMBOPHILLIA
Start date (dd MMM yyyy)	21 NOV 2008
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)	NOV 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	THROMBUS
Start date (dd MMM yyyy)	UN NOV 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 NOV 2008
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2007
Start Year (derived)	2007
Stop Month and Year (derived)	NOV 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	MORPHINE ALLERGY (ITCHING AND CRAWLING FEELING)
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1990
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	RECURRENT KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	GASTRIC SLEEVE
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	ABDOMINOPLASTY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	BREAST AUGMENTATION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Condition	MULTIPLE PULMONARY EMBOLISMS
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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:50 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:50
Height (<i>xxx.x</i>)	66.5 in
Weight (<i>xxx.x</i>)	180.6 lb
BMI (<i>xxx.x</i>)	28.77295 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:14:07

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 00:14:07

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Date of assessment (dd MMM yyyy) 18 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:14:07

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:14:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 143948

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

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)	18 AUG 2020
Time of assessment (00:00-23:59)	16:50 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:50
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	19:00 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 19:00
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 18 AUG 2020

What was the treatment time? (00:00-23:59) 18:21 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 18:21

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 AUG 2020

Collection time (00:00-23:59)

17:16 (24 HR)

Collection date and time (derived)

18 AUG 2020 17:16

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:12	18 AUG 2020 17:12
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 19:05

PC Open Date & Time

18 AUG 2020 18:41

PC Close Date & Time

18 AUG 2020 21:11

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

18 AUG 2020 22:06

PC Close Date & Time

19 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

19 AUG 2020 22:34

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

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

97.6 °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

20 AUG 2020 22:41

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

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

97.6 °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

22 AUG 2020 07:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 23:59

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 21:50

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 22:41

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 19:05

PC Open Date & Time

18 AUG 2020 18:41

PC Close Date & Time

18 AUG 2020 21:11

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 AUG 2020 22:06

PC Close Date & Time

19 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 22:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 22:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

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

22 AUG 2020 07:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 00:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 21:50

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 22:41

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 19:06
PC Open Date & Time	18 AUG 2020 18:41
PC Close Date & Time	18 AUG 2020 21:11

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

18 AUG 2020 22:06

PC Close Date & Time

19 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:36
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 22:43
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

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 ☒

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 07:20
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

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)

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US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 09:56
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 22:42
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

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)	21 SEP 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:17
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:50
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3442031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 11:20 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 11:20

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

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	10:25 (24 HR)
Collection date and time (derived)	21 SEP 2020 10:25

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	21 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3442031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 11:59

PC Open Date & Time

21 SEP 2020 11:40

PC Close Date & Time

21 SEP 2020 14:10

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 97.5 °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	21 SEP 2020 21:47
PC Open Date & Time	21 SEP 2020 15:05
PC Close Date & Time	22 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

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	99.5 °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	22 SEP 2020 22:40
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

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

99.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 SEP 2020 22:33

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 22:26

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

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

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

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:10

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

28 SEP 2020 07:52

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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

21 SEP 2020 11:59

PC Open Date & Time

21 SEP 2020 11:40

PC Close Date & Time

21 SEP 2020 14:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:48

PC Open Date & Time

21 SEP 2020 15:05

PC Close Date & Time

22 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 22:41

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 22:34

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

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

24 SEP 2020 22:27

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 ☐

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

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

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

26 SEP 2020 12:11

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

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

28 SEP 2020 07:52

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 12:00
PC Open Date & Time	21 SEP 2020 11:40
PC Close Date & Time	21 SEP 2020 14:10

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 21:49
PC Open Date & Time	21 SEP 2020 15:05
PC Close Date & Time	22 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 22:42
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 22:35
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 22:27
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

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)

111 of 2435

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

Yes ☐

PC Time stamp

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

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 ☒

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 07:53
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

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) _____

US3442031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

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.

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 OCT 2020
Collection time (00:00-23:59)	09:52 (24 HR)
Collection date and time (derived)	16 OCT 2020 09:52

US3442031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:08

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 OCT 2020 16:38:51

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

27 OCT 2020 12:01:01

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 10:57:30

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	17 NOV 2020 12:00:52
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

26 NOV 2020 09:17:29

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

03 DEC 2020 19:31:38

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

14 DEC 2020 18:38:57

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 07:13:00

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 18:00:53

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

02 JAN 2021 15:54:35

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

07 JAN 2021 06:39:40

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

15 JAN 2021 11:42:33

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 13:02:19

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 22:37:17
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

07 FEB 2021 11:08:59

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 12:01:49

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

20 FEB 2021 14:20:21

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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	27 FEB 2021 18:08:12
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 08:50:57

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

11 MAR 2021 10:07:48

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 12:07:33

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

29 MAR 2021 12:00:51

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

03 APR 2021 12:17:57

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

08 APR 2021 20:16:10

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

18 APR 2021 19:22:03

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

22 APR 2021 08:38:08

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

03 MAY 2021 22:24:30

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 320

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 AUG 2021 00:01
Patient Cloud Close Date & Time	09 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 MAR 2022 00:01
Patient Cloud Close Date & Time	07 MAR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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°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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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="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"/>

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

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

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3442031

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:43:19

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		27 FEB 2021 18:08:40

US3442031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:14:07

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 21:26:26

Generated On: 09 Jun 2021 17:43:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3442031

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 21:26:26

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 15:17:05

Generated On: 09 Jun 2021 17:43:19

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

Visit date (dd MMM yyyy)	8 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
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US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 15:17:05

Generated On: 09 Jun 2021 17:43:19

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) _____

US3442031

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 15:17:05

Generated On: 09 Jun 2021 17:43:19

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.

US3442031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 15:17:05

Generated On: 09 Jun 2021 17:43:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 MAR 2021
Collection time (00:00-23:59)	12:18 (24 HR)
Collection date and time (derived)	8 MAR 2021 12:18

US3442031

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 15:17:05

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3442031

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3442031

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:43:19

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"/>

US3442031

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:43:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3442031

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:14:06

Generated On: 09 Jun 2021 17:43:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3442031

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

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:26:26

Generated On: 09 Jun 2021 17:43:19

Date of updated informed consent (dd MMM yyyy) 4 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) 4 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 _____

US3442031

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:14:06

Generated On: 09 Jun 2021 17:43:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 JAN 2021

Collection time (00:00-23:59)

09:51 (24 HR)

Collection date and time (derived)

4 JAN 2021 09:51

US3442031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 00:14:06

Generated On: 09 Jun 2021 17:43:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00 - 23:59)	09:52
Collection Date and Time (derived)	4 JAN 2021 09:52

US3442031

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 00:14:06

Generated On: 09 Jun 2021 17:43:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

AEID

Adverse event

HEAT AT INJECTION SITE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

AEID

Adverse event

LYMPHADENOPATHY RIGHT
AXILLA- IPSILATERAL TO
VACCINATION SITE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

AEID	USA-US017-2020-MRNA-1273-P30 1000003
Adverse event	DEEP VEIN THROMBOSIS (LEFT LEG)
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)	3 NOV 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)	4 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	4 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HOSPITALIZED OVERNIGHT FOR DEEP VEIN THROMBOSIS. SUBJECT WAS RELEASED AND MEDICAL RECORDS HAVE BEEN REQUESTED.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Feb 2021 00:14:05

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

AEID	USA-US017-2020-MRNA-1273-P30 1000003
Adverse event	PULMONARY EMBOLISM
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)	3 NOV 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)	4 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	3 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	4 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

AEID

Adverse event

SHORTNESS OF BREATH

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

4 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	26 AUG 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)	27 AUG 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	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 13 Feb 2021 00:14:05

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 00:14:06

Generated On: 09 Jun 2021 17:43:19

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

Yes ☒

No ☐

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

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication PROTONIX (PANTOPRAZOLE)

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication AMITRIPTYLINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 17:39:48

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Name of Medication ASA

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 AUG 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"/>

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication ELEVATED TEMPERATURE,
BODY ACHES, FATIGUE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 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)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication APIXABAN

Prophylaxis Yes ☒
No ☐

Indication PULMONARY EMBOLISM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication LEFT CALF PAIN (SECONDARY
TO DEEP VEIN THROMBOSIS)

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication APIXABAN

Prophylaxis Yes ☒
No ☐

Indication PULMONARY EMBOLISM

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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)		12 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication ENOXAPARIN SODIUM

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLISM

Dose per administration 77.273

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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 NOV 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 NOV 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"/>

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLISM

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

Q4H

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

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US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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 NOV 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 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication KETOROLAC TROMETHAMINE

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLISM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLISM

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

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

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☒
No ☐

Indication DEEP VENOUS THROMBOSIS
(PROPHYLAXIS)

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication AL HYDROX/ MG HYDROX/
SIMETHICONE

Prophylaxis Yes ☒
No ☐

Indication GASTROINTESTINAL
PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication MAGNESIUM HYDROXIDE

Prophylaxis Yes ☒
No ☐

Indication GASTROINTESTINAL
PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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)	04 NOV 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 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication ONDANSETRON HCL

Prophylaxis Yes ☒
No ☐

Indication GASTROINTESTINAL
PROPHYLAXIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

6 TIMES DAILY

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication PULMONARY EMBOLISM

Dose per administration 243

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 17:39:48

Generated On: 09 Jun 2021 17:43:19

	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 NOV 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 NOV 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"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 00:14:06

Generated On: 09 Jun 2021 17:43:19

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Feb 2021 00:14:06

Generated On: 09 Jun 2021 17:43:19

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
03 NOV 2020	CT SCAN - ANGIO CHEST W&WO CONT	Diagnostic	
3 NOV 2020	CHEST X-RAY	Diagnostic	
3 NOV 2020	ECG	Diagnostic	
3 NOV 2020	ULTRA SOUND	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:43:19

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:43:19

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 ☐

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 17:39:49

Generated On: 09 Jun 2021 17:43:19

SAEID	USA-US017-2020-MRNA-1273-P301000003
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)	3

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 17:39:49

Generated On: 09 Jun 2021 17:43:19

SAEID	USA-US017-2020-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	09/NOV/2020 18:02
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

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 17:39:49

Generated On: 09 Jun 2021 17:43:19

SAEID	USA-US017-2020-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	16/NOV/2020 12:57
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

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 17:39:49

Generated On: 09 Jun 2021 17:43:19

SAEID	USA-US017-2020-MRNA-1273-P301000003
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)	3
Date of submission (Pre-filled from custom function)	10/DEC/2020 14:34
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

US3442031 (Prod: Benchmark Research - Fort Worth)

US3442031

Form: Participant Creation

Generated On: 09 Jun 2021 17:43:19

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'US3442031'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 21:39:18

US3442031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:02

US3442031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 21:39:19

US3442031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Clinic (Clinic)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:02

US3442031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'SCRN'	System	18 Aug 2020 22:57:02

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered (b) (6) 1965'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 21:39:20

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '55'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'YEARS'	System	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '55'	System	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Female (F)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'I'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:43:19

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:29

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Aug 2020'	System	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2020'	System	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Amendment 2 (2)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:44

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 21:39:19

US3442031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:43:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'I'	System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:43:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:14:55

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:41:54
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Coagulopathies, PT: Hypercoagulation, LLT: Thrombophilia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:48:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:48:24
Data point term sent to Coder	System	18 Aug 2020 23:18:48
User entered 'THROMBOPHILLIA'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:42:52
User entered '21 Nov 2008'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:41:56
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:41:57
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:41:58
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:42:00
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Nov 2008'	System	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2008'	System	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	18 Aug 2020 23:18:48

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:14
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Thrombus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:36:40
Data point term sent to Coder	System	18 Aug 2020 23:19:49
User entered 'THROMBUS'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:16
User entered 'UN Nov 2007'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:17
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:19
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:20
User entered 'UN Nov 2008'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:21
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Nov 2007'	System	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2007'	System	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Nov 2008'	System	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2008'	System	18 Aug 2020 23:19:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:27
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:36:40
Data point term sent to Coder	System	18 Aug 2020 23:21:52
User entered 'HEARTBURN'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:29
User entered 'UN UNK 2016'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:30
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:32
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:33
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:35
User entered '0'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2016'	System	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2016'	System	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	18 Aug 2020 23:21:30

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:33:47
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)	19 Aug 2020 00:45:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 00:45:18
Data point term sent to Coder	System	19 Aug 2020 00:44:24
User entered 'Hypothyroidism'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:33:48
User entered 'un UNK 2017'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:33:49
User entered '0'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:33:51
User entered 'Yes (Y)'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:33:52
User entered empty.	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:33:54
User entered '0'	Alma Guel (b) (4)	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2017'	System	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2017'	System	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	19 Aug 2020 00:44:00

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:55
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:01:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:01:36
Data point term sent to Coder	System	25 Aug 2020 15:00:42
User entered 'CHOLELITHIASIS'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:56
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:57
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:09:59
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:10:00
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:10:01
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2013'	System	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2013'	System	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2013'	System	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2013'	System	25 Aug 2020 14:59:44

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:36:18
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:08:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:08:34
Data point term sent to Coder	System	25 Aug 2020 15:08:05
User entered 'ANXIETY'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:37:02
User entered 'UN UNK 2016' reason for change:	John Villegas (b) (4)	01 Oct 2020 17:29:32
Data Entry Error	(b) (4)	
User entered 'UN UNK 2017'	Melody Dufrene (b) (4)	25 Aug 2020 15:07:06
	(b) (4)	

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:37:03
User entered '0'	Melody Dufrene (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:37:04
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:37:06
User entered empty.	Melody Dufrene (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:37:07
User entered '0'	Melody Dufrene (b) (4)	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2016'	System	01 Oct 2020 17:29:32
User entered 'Jan 2017'	System	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2016'	System	01 Oct 2020 17:29:32
User entered '2017'	System	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	25 Aug 2020 15:07:06

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:16:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:16:35
Data point term sent to Coder	System	25 Aug 2020 15:15:21
User entered 'APPENDECTOMY'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:07:57
User entered 'UN UNK 2010'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:07:59
User entered '0'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:08:00
User entered 'No (N)'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:08:01
User entered 'UN UNK 2010'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:08:03
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2010'	System	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2010'	System	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2010'	System	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2010'	System	25 Aug 2020 15:14:25

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:37
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)	25 Aug 2020 15:16:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:16:35
Data point term sent to Coder	System	25 Aug 2020 15:15:21
User entered 'APPENDICITIS'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:07:41
User entered 'UN UNK 2010'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:39
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:43
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:07:44
User entered 'UN UNK 2010'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:07:45
User entered '0'	Melody Dufrene (b) (4)	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2010'	System	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2010'	System	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2010'	System	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2010'	System	25 Aug 2020 15:14:58

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:08:24
User coded data point as SOC: Surgical and medical procedures, HLT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:17:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:17:30
Data point term sent to Coder	System	25 Aug 2020 15:16:23
User entered 'CHOLECYSTECTOMY'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:08:25
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:08:27
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:08:28
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:08:29
User entered 'UN UNK 2013'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:08:31
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2013'	System	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2013'	System	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2013'	System	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2013'	System	25 Aug 2020 15:15:37

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 17:10:25
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 20:57:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 20:57:59
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 14:21:38
User entered 'post-menopausal'	(b) (4), (b) (6)	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:10:27
User entered 'un UNK 2010'		08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:10:28
User entered '0'		08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:10:29
User entered 'Yes (Y)'		08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:10:31
User entered empty.		08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:10:32
User entered '0'		08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2010'	System	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2010'	System	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	08 Oct 2020 14:21:34

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:47:18
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 19:03:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 19:03:51
Data point term sent to Coder	System	14 Nov 2020 16:36:20
User entered 'Morphine Allergy (Itching and crawling feeling)'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:48:39
User entered 'un UNK 1992'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:48:40
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:48:41
User entered 'Yes (Y)'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:48:42
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:48:44
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 1992'	System	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '1992'	System	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	14 Nov 2020 16:36:19

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:03:24
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:37:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:37:50
Data point term sent to Coder	System	14 Nov 2020 16:37:21
User entered 'Obesity'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:03:26
User entered 'un UNK 1990'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:03:30
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:03:31
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:03:33
User entered 'un UNK 2012'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:03:34
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 1990'	System	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '1990'	System	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2012'	System	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2012'	System	14 Nov 2020 16:37:06

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:50:24
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis recurrent - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:38:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:38:50
Data point term sent to Coder	System	14 Nov 2020 16:38:22
User entered 'Recurrent Kidney Stones'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:50:25
User entered 'un UNK 1982'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:50:26
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:50:28
User entered 'Yes (Y)'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:50:29
User entered empty.	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:50:31
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 1982'	System	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '1982'	System	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	14 Nov 2020 16:37:55

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:50:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:39:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:39:50
Data point term sent to Coder	System	14 Nov 2020 16:39:22
User entered 'Gastric Sleeve'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:50:54
User entered 'un UNK 2012'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:50:55
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:50:57
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:50:58
User entered 'un UNK 2012'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:50:59
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2012'	System	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2012'	System	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2012'	System	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2012'	System	14 Nov 2020 16:38:40

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:51:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Abdominal therapeutic procedures NEC, PT: Abdominoplasty, LLT: Abdominoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:40:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:40:57
Data point term sent to Coder	System	14 Nov 2020 16:40:23
User entered 'abdominoplasty'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:51:31
User entered 'un UNK 2015'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:51:32
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:51:33
User entered 'No (N)'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:51:35
User entered 'un UNK 2015'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:51:36
User entered '0'	Alma Guel (b) (4)	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2015'	System	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2015'	System	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2015'	System	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2015'	System	14 Nov 2020 16:39:24

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:03:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:03:04
Data point term sent to Coder	System	23 Nov 2020 19:29:24
User entered 'Breast Augmentation'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:08
User entered 'un UNK 2015'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:10
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:12
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:13
User entered 'un UNK 2015'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:07:14
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2015'	System	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2015'	System	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2015'	System	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2015'	System	23 Nov 2020 19:29:23

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 14:18:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 14:18:49
Data point term sent to Coder	System	04 Dec 2020 18:12:22
User entered 'Multiple Pulmonary Embolisms'	Alma Guel (b) (4)	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'un UNK 2007'	(b) (4) Alma Guel (b) (4)	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Alma Guel (b) (4)	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'un UNK 2007'	(b) (4) Alma Guel (b) (4)	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2007'	System	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2007'	System	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'Jan 2007'	System	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '2007'	System	04 Dec 2020 18:12:03

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '16:50'	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '18 Aug 2020 16:50'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '66.5' in	(b) (4)	
	Melody Dufrene (b) (4)	25 Aug 2020 15:17:52
	(b) (4)	
DataPoint set to visible.	System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '180.6' lb	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:17:52
DataPoint set to visible.	(b) (4) System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
Amendment Manager: User entered '28.77295'	System	17 Sep 2020 00:13:09
User entered '28.8'	System	25 Aug 2020 15:17:52
DataPoint set to visible.	System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'kg/m2'	System	25 Aug 2020 15:17:52
DataPoint set to visible.	System	18 Aug 2020 22:57:49

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'bpm'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'breaths/min'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'mmHg'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'mmHg'	System	25 Aug 2020 15:17:52

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26

US3442031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26

US3442031

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:18:15

US3442031

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:18:15

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:19

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:19

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 12:16:43
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'done' (Site from DM).		08 Oct 2020 14:22:50
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		08 Oct 2020 07:27:41
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:19

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:19

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'UN UNK 2010'	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:43:19

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:20:13

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

[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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

[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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

[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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

[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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'I'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:43:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:02:31

US3442031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:58:01

US3442031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:58:01

US3442031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Melody Dufrene (b) (4)	18 Aug 2020 22:58:05
User entered 'Home (Home)'	(b) (4)	
	Melody Dufrene (b) (4)	18 Aug 2020 22:58:01
	(b) (4)	

US3442031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'VISIT1'	System	18 Aug 2020 22:58:01

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 22:39:27

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:27:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:27:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 22:39:27
User entered '143948' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 22:39:27

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 05:48:39
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'correction submitted to endpoint' (Site from System).		05 Oct 2020 23:14:57
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:00:06
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 21:00:06
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	18 Aug 2020 22:59:06
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 22:39:27

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

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)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

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)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 22:59:06

US3442031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:43:19

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:53:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:25:31

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '16:50'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '18 Aug 2020 16:50'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '97.4' F	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '71'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'bpm'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '14'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'breaths/min'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '116'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'mmHg'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '81'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'mmHg'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:43:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered missing code ND - Not Done.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User accepted default value 'Post-Dose (POSTDOSE)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '19:00'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '18 Aug 2020 19:00'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 09:57:32
Query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' answered with 'Temp is correct as entered. It was rechecked and remained the same. It is not clinically significant.' (Site from DM).		29 Sep 2020 19:58:05
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 12:46:31
User opened query 'Per CDM, Response noted; However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate.' (Site from DM).		21 Sep 2020 12:46:27
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. It was rechecked and remained the same.' (Site from System).		17 Sep 2020 15:16:39
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 00:13:09
User entered '96.7' F	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '76'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'bpm'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '13'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'breaths/min'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '121'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'mmHg'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '80'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'mmHg'	System	25 Aug 2020 15:22:53

US3442031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:23:03

US3442031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:23:03

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

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)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18:21'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '18 Aug 2020 18:21'	System	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Melody Dufrene (b) (4)	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'ONCE'	System	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 23:23:35

US3442031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:23:56

US3442031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:23:56

US3442031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '17:16'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:23:56

US3442031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '18 Aug 2020 17:16'	System	25 Aug 2020 15:23:56

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:43:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '18 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '17:12'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '18 Aug 2020 17:12'	System	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered empty.	System	25 Aug 2020 15:24:13

US3442031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	25 Aug 2020 15:24:19

US3442031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	25 Aug 2020 15:24:19

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:04:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bf032f60-d4e9-4a03-bfd8-65e03a71a89f' User entered 'Yes (Y)'	System	19 Aug 2020 00:05:22
	System	19 Aug 2020 00:05:22

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bf032f60-d4e9-4a03-bfd8-65e03a71a89f' User entered '97.4'	System	19 Aug 2020 00:05:22
	System	19 Aug 2020 00:05:22

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bf032f60-d4e9-4a03-bfd8-65e03a71a89f'	System	19 Aug 2020 00:05:22
User entered 'No (N)'	System	19 Aug 2020 00:05:22

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:20', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bf032f60-d4e9-4a03-bfd8-65e03a71a89f' User entered '18 Aug 2020 19:05'	System	19 Aug 2020 00:05:22
	System	19 Aug 2020 00:05:22

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 18:41'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 21:11'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 22:06'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 2'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:33:43', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f7b8f7ae-361f-4a8f-99f2-f698c42d4735'	System	20 Aug 2020 03:34:06
User entered 'Yes (Y)'	System	20 Aug 2020 03:34:06

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:33:51', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f7b8f7ae-361f-4a8f-99f2-f698c42d4735'	System	20 Aug 2020 03:34:06
User entered '96.5'	System	20 Aug 2020 03:34:06

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:33:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f7b8f7ae-361f-4a8f-99f2-f698c42d4735'	System	20 Aug 2020 03:34:06
User entered 'No (N)'	System	20 Aug 2020 03:34:06

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:34:04', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f7b8f7ae-361f-4a8f-99f2-f698c42d4735'	System	20 Aug 2020 03:34:06
User entered '19 Aug 2020 22:34'	System	20 Aug 2020 03:34:06

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 3'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:41:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'dae87378-bccc-4287-b80d-3927c83d8c9d' User entered 'Yes (Y)'	System	21 Aug 2020 03:41:39
	System	21 Aug 2020 03:41:39

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:41:19', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'dae87378-bccc-4287-b80d-3927c83d8c9d' User entered '97.6'	System	21 Aug 2020 03:41:39
	System	21 Aug 2020 03:41:39

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:41:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'dae87378-bccc-4287-b80d-3927c83d8c9d'	System	21 Aug 2020 03:41:39
User entered 'No (N)'	System	21 Aug 2020 03:41:39

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:41:34', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'dae87378-bccc-4287-b80d-3927c83d8c9d' User entered '20 Aug 2020 22:41'	System	21 Aug 2020 03:41:39
	System	21 Aug 2020 03:41:39

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 4'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:19:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c9f27a2f-00ee-4bb0-abce-8f1b8e6e10c5'	System	22 Aug 2020 12:20:08
User entered 'Yes (Y)'	System	22 Aug 2020 12:20:08

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:19:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c9f27a2f-00ee-4bb0-abce-8f1b8e6e10c5' User entered '97.6'	System	22 Aug 2020 12:20:08
	System	22 Aug 2020 12:20:08

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:19:57', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c9f27a2f-00ee-4bb0-abce-8f1b8e6e10c5'	System	22 Aug 2020 12:20:08
User entered 'No (N)'	System	22 Aug 2020 12:20:08

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c9f27a2f-00ee-4bb0-abce-8f1b8e6e10c5'	System	22 Aug 2020 12:20:08
User entered '22 Aug 2020 07:20'	System	22 Aug 2020 12:20:08

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 5'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T23:59:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '776893fc-f67d-4375-b31d-62175c1cd433'	System	23 Aug 2020 04:59:56
User entered 'Yes (Y)'	System	23 Aug 2020 04:59:56

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T23:59:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '776893fc-f67d-4375-b31d-62175c1cd433'	System	23 Aug 2020 04:59:56
User entered '97.8'	System	23 Aug 2020 04:59:56

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T23:59:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '776893fc-f67d-4375-b31d-62175c1cd433'	System	23 Aug 2020 04:59:56
User entered 'No (N)'	System	23 Aug 2020 04:59:56

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T23:59:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '776893fc-f67d-4375-b31d-62175c1cd433'	System	23 Aug 2020 04:59:56
User entered '22 Aug 2020 23:59'	System	23 Aug 2020 04:59:56

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 6'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4b972f10-173a-4b72-9376-bbfb2ee39b62'	System	24 Aug 2020 02:50:29
User entered 'Yes (Y)'	System	24 Aug 2020 02:50:29

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4b972f10-173a-4b72-9376-bbfb2ee39b62' User entered '97.8'	System	24 Aug 2020 02:50:29
	System	24 Aug 2020 02:50:29

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4b972f10-173a-4b72-9376-bbfb2ee39b62'	System	24 Aug 2020 02:50:29
User entered 'No (N)'	System	24 Aug 2020 02:50:29

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:26', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4b972f10-173a-4b72-9376-bbfb2ee39b62'	System	24 Aug 2020 02:50:29
User entered '23 Aug 2020 21:50'	System	24 Aug 2020 02:50:29

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 7'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f93240aa-e4c7-4ae9-9ebd-9126ffdd32a6'	System	25 Aug 2020 03:41:28
User entered 'Yes (Y)'	System	25 Aug 2020 03:41:28

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f93240aa-e4c7-4ae9-9ebd-9126ffdd32a6' User entered '97.7'	System	25 Aug 2020 03:41:28
	System	25 Aug 2020 03:41:28

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f93240aa-e4c7-4ae9-9ebd-9126ffdd32a6'	System	25 Aug 2020 03:41:28
User entered 'No (N)'	System	25 Aug 2020 03:41:28

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:27', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f93240aa-e4c7-4ae9-9ebd-9126ffdd32a6'	System	25 Aug 2020 03:41:28
User entered '24 Aug 2020 22:41'	System	25 Aug 2020 03:41:28

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf'	System	19 Aug 2020 00:05:48
User entered 'None (1)'	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:34', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf' User entered 'No (N)'	System	19 Aug 2020 00:05:48
	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf'	System	19 Aug 2020 00:05:48
User entered 'No (N)'	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:41', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf'	System	19 Aug 2020 00:05:48
User entered 'None (1)'	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:44', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ef41d5fd-bace-4772-804d-5e8371e96fbf' User entered '18 Aug 2020 19:05'	System	19 Aug 2020 00:05:48
	System	19 Aug 2020 00:05:48

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 18:41'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 21:11'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 22:06'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 2'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:34:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:34:29', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered 'No (N)'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:34:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered 'No (N)'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered 'None (1)'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:27', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2843c14e-4fef-4dc5-9ca0-1cd3a4e1f33e'	System	20 Aug 2020 03:35:28
User entered '19 Aug 2020 22:35'	System	20 Aug 2020 03:35:28

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 3'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:11', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead'	System	21 Aug 2020 03:42:35
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead' User entered 'No (N)'	System	21 Aug 2020 03:42:35
	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead' User entered 'No (N)'	System	21 Aug 2020 03:42:35
	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead' User entered 'None (1)'	System	21 Aug 2020 03:42:35
	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6978ce2d-1349-4024-b82c-5c2bd6b61ead' User entered '20 Aug 2020 22:42'	System	21 Aug 2020 03:42:35
	System	21 Aug 2020 03:42:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 4'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered 'No (N)'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered 'No (N)'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered 'None (1)'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0b8ea75e-7174-4696-84b1-4376a91a3db7'	System	22 Aug 2020 12:20:30
User entered '22 Aug 2020 07:20'	System	22 Aug 2020 12:20:30

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 5'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered 'None (1)'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered 'No (N)'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:09', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered 'No (N)'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered 'None (1)'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7602ada6-ef4c-4eb2-ac72-a19725587408'	System	23 Aug 2020 05:00:21
User entered '23 Aug 2020 00:00'	System	23 Aug 2020 05:00:21

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 6'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba' User entered 'None (1)'	System	24 Aug 2020 02:50:51
	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba' User entered 'No (N)'	System	24 Aug 2020 02:50:51
	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:41', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba' User entered 'No (N)'	System	24 Aug 2020 02:50:51
	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba' User entered 'None (1)'	System	24 Aug 2020 02:50:51
	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T21:50:49', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f546132e-a350-4ade-a309-9d699381f9ba' User entered '23 Aug 2020 21:50'	System	24 Aug 2020 02:50:51
	System	24 Aug 2020 02:50:51

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 7'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:33', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered 'None (1)'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:36', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered 'No (N)'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered 'No (N)'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3'	System	25 Aug 2020 03:41:50
User entered 'None (1)'	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:49', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1cf52855-0429-4a6e-987e-c5f4609afdc3' User entered '24 Aug 2020 22:41'	System	25 Aug 2020 03:41:50
	System	25 Aug 2020 03:41:50

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077' User entered 'None (0)'	System	19 Aug 2020 00:06:19
	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077' User entered 'None (0)'	System	19 Aug 2020 00:06:19
	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:05:59', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:06:01', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:06:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'None (0)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:06:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered 'No (N)'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-18T19:06:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2ed3b29e-4ff0-4a93-8a61-4094a8866077'	System	19 Aug 2020 00:06:19
User entered '18 Aug 2020 19:06'	System	19 Aug 2020 00:06:19

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 18:41'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 21:11'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '18 Aug 2020 22:06'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 2'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:39', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe' User entered 'None (0)'	System	20 Aug 2020 03:36:50
	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'No interference with activity (1)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:35:57', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbc' User entered 'None (0)'	System	20 Aug 2020 03:36:50
	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:04', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbc' User entered 'None (0)'	System	20 Aug 2020 03:36:50
	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe' User entered 'None (0)'	System	20 Aug 2020 03:36:50
	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:37', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered 'No (N)'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-19T22:36:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '455c59bb-f4e4-4b4a-9a6f-7373ea095fbe'	System	20 Aug 2020 03:36:50
User entered '19 Aug 2020 22:36'	System	20 Aug 2020 03:36:50

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 3'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:42:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:43:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:43:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'None (0)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:43:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered 'No (N)'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-20T22:43:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3787c56d-e714-4a3f-8e35-aa6d6929fc88'	System	21 Aug 2020 03:43:20
User entered '20 Aug 2020 22:43'	System	21 Aug 2020 03:43:20

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 4'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01' User entered 'None (0)'	System	22 Aug 2020 12:21:01
	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered 'None (0)'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:42', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01' User entered 'None (0)'	System	22 Aug 2020 12:21:01
	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01' User entered 'None (0)'	System	22 Aug 2020 12:21:01
	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01' User entered 'None (0)'	System	22 Aug 2020 12:21:01
	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:51', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01' User entered 'None (0)'	System	22 Aug 2020 12:21:01
	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:54', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01' User entered 'No (N)'	System	22 Aug 2020 12:21:01
	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-22T07:20:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '35c85e60-edd7-4d4c-bb4c-6925c2b33d01'	System	22 Aug 2020 12:21:01
User entered '22 Aug 2020 07:20'	System	22 Aug 2020 12:21:01

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 5'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'None (0)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608' User entered 'None (0)'	System	23 Aug 2020 05:00:53
	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608' User entered 'None (0)'	System	23 Aug 2020 05:00:53
	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:34', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608' User entered 'None (0)'	System	23 Aug 2020 05:00:53
	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608' User entered 'None (0)'	System	23 Aug 2020 05:00:53
	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608' User entered 'None (0)'	System	23 Aug 2020 05:00:53
	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:44', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered 'No (N)'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-23T00:00:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9ba3e8bd-9d21-4a59-ae82-862a988fd608'	System	23 Aug 2020 05:00:53
User entered '23 Aug 2020 00:00'	System	23 Aug 2020 05:00:53

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 6'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered 'None (0)'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered 'None (0)'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered 'None (0)'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:19', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered 'None (0)'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered 'None (0)'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered 'None (0)'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d'	System	24 Aug 2020 14:56:37
User entered 'No (N)'	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T09:56:34', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5a31f7c1-7458-4a85-907f-8e8afb72668d' User entered '24 Aug 2020 09:56'	System	24 Aug 2020 14:56:37
	System	24 Aug 2020 14:56:37

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 7'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:41:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'None (0)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered 'No (N)'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-08-24T22:42:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '2e1da49c-36a7-436c-a4fa-194ebd4e0f3f' User entered '24 Aug 2020 22:42'	System	25 Aug 2020 03:42:22
	System	25 Aug 2020 03:42:22

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 23:23:35

US3442031

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	28 Aug 2020 18:01:22

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '28 Aug 2020'	(b) (4) Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 18:01:22

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Melody Dufrene (b) (4)	28 Aug 2020 18:01:22

US3442031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 18:01:22

US3442031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	28 Aug 2020 18:01:27

US3442031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	28 Aug 2020 18:01:27

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:16:44

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:16:44

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:16:44

US3442031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 14:16:44

US3442031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 14:16:50

US3442031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	04 Sep 2020 14:16:50

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:50:18

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:50:18

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:50:18

US3442031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 16:50:18

US3442031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:50:25

US3442031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	11 Sep 2020 16:50:25

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:13:44

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:13:44

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Clinic (Clinic)'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:13:44

US3442031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'VISIT2'	System	21 Sep 2020 17:13:44

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User accepted default value 'Pre-Dose (PREDOSE)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '10:17'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '21 Sep 2020 10:17'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '97.4' F	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '65'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'bpm'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '12'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'breaths/min'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '121'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'mmHg'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '85'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'mmHg'	System	21 Sep 2020 17:15:10

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User accepted default value 'Post-Dose (POSTDOSE)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '21 Sep 2020'	(b) (4) Melody Dufrene (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '11:50'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '21 Sep 2020 11:50'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '97.3' F	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Oral (Oral)'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '71'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'bpm'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '12'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'breaths/min'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '116'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'mmHg'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '82'	Melody Dufrene (b) (4) (b) (4)	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'mmHg'	System	22 Sep 2020 21:41:30

US3442031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	21 Sep 2020 17:15:19

US3442031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:19

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

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)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '21 Sep 2020'	(b) (4) Melody Dufrene (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '11:20'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '21 Sep 2020 11:20'	System	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Right Arm (RIGHT ARM)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'ONCE'	System	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:43:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 16:28:53

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:50

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:50

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '10:25'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:15:50

US3442031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '21 Sep 2020 10:25'	System	21 Sep 2020 17:15:50

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:43:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered '21 Sep 2020'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '10:30'	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '21 Sep 2020 10:30'	System	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Melody Dufrene (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Melody Dufrene (b) (4) (b) (4)	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered empty.	System	21 Sep 2020 17:16:06

US3442031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Melody Dufrene (b) (4)	21 Sep 2020 17:16:12

US3442031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	21 Sep 2020 17:16:12

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:58:42', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0e4275c7-856c-49d0-8cfd-c811c12c3abc' User entered 'Yes (Y)'	System	21 Sep 2020 16:59:07
	System	21 Sep 2020 16:59:07

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:58:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0e4275c7-856c-49d0-8cfd-c811c12c3abc' User entered '97.3'	System	21 Sep 2020 16:59:07
	System	21 Sep 2020 16:59:07

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:58:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0e4275c7-856c-49d0-8cfd-c811c12c3abc'	System	21 Sep 2020 16:59:07
User entered 'No (N)'	System	21 Sep 2020 16:59:07

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:05', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0e4275c7-856c-49d0-8cfd-c811c12c3abc' User entered '21 Sep 2020 11:59'	System	21 Sep 2020 16:59:07
	System	21 Sep 2020 16:59:07

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 14:10'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:09', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '536ba1c3-b20d-491a-9948-bdda3bd9a8b4'	System	22 Sep 2020 02:47:33
User entered 'Yes (Y)'	System	22 Sep 2020 02:47:33

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:19', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '536ba1c3-b20d-491a-9948-bdda3bd9a8b4' User entered '97.5'	System	22 Sep 2020 02:47:33
	System	22 Sep 2020 02:47:33

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '536ba1c3-b20d-491a-9948-bdda3bd9a8b4'	System	22 Sep 2020 02:47:33
User entered 'No (N)'	System	22 Sep 2020 02:47:33

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '536ba1c3-b20d-491a-9948-bdda3bd9a8b4'	System	22 Sep 2020 02:47:33
User entered '21 Sep 2020 21:47'	System	22 Sep 2020 02:47:33

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 15:05'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 2'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a' User entered 'Yes (Y)'	System	23 Sep 2020 03:41:01
	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:33', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a' User entered '99.5'	System	23 Sep 2020 03:41:01
	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:37', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a'	System	23 Sep 2020 03:41:01
User entered 'Yes (Y)'	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
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 'med added. logs updated.' (Site from System).		14 Oct 2020 06:00:09
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:46', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a' User entered '1'	System	23 Sep 2020 03:41:01
	System	23 Sep 2020 03:41:01
	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:46', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a' User entered '0'	System	23 Sep 2020 03:41:01
	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:40:57', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c312159-7ee8-4cb4-8b28-807dd1c3946a'	System	23 Sep 2020 03:41:01
User entered '22 Sep 2020 22:40'	System	23 Sep 2020 03:41:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 3'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered 'Yes (Y)'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:20', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered '99.5'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered 'Yes (Y)'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
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 'med added. logs updated.' (Site from System).		14 Oct 2020 06:00:13
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered '1'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered '0'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:39', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7eee96a6-1de5-4793-ad55-6bb13f13fc2f' User entered '23 Sep 2020 22:33'	System	24 Sep 2020 03:33:41
	System	24 Sep 2020 03:33:41

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 4'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8a65e276-ee3f-4f14-9ba2-4b382221e110'	System	25 Sep 2020 03:26:38
User entered 'Yes (Y)'	System	25 Sep 2020 03:26:38

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8a65e276-ee3f-4f14-9ba2-4b382221e110' User entered '97.7'	System	25 Sep 2020 03:26:38
	System	25 Sep 2020 03:26:38

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8a65e276-ee3f-4f14-9ba2-4b382221e110'	System	25 Sep 2020 03:26:38
User entered 'No (N)'	System	25 Sep 2020 03:26:38

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8a65e276-ee3f-4f14-9ba2-4b382221e110'	System	25 Sep 2020 03:26:38
User entered '24 Sep 2020 22:26'	System	25 Sep 2020 03:26:38

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 5'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 6'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:10:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ced9a78b-4c21-45f5-953c-118956917b36'	System	26 Sep 2020 17:10:56
User entered 'Yes (Y)'	System	26 Sep 2020 17:10:56

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:10:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ced9a78b-4c21-45f5-953c-118956917b36' User entered '97.4'	System	26 Sep 2020 17:10:56
	System	26 Sep 2020 17:10:56

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:10:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ced9a78b-4c21-45f5-953c-118956917b36'	System	26 Sep 2020 17:10:56
User entered 'No (N)'	System	26 Sep 2020 17:10:56

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:10:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'ced9a78b-4c21-45f5-953c-118956917b36'	System	26 Sep 2020 17:10:56
User entered '26 Sep 2020 12:10'	System	26 Sep 2020 17:10:56

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 7'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '93030341-dd52-4290-aa72-f5edbe9a50e0'	System	28 Sep 2020 12:52:37
User entered 'Yes (Y)'	System	28 Sep 2020 12:52:37

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '93030341-dd52-4290-aa72-f5edbe9a50e0' User entered '97.5'	System	28 Sep 2020 12:52:37
	System	28 Sep 2020 12:52:37

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '93030341-dd52-4290-aa72-f5edbe9a50e0'	System	28 Sep 2020 12:52:37
User entered 'No (N)'	System	28 Sep 2020 12:52:37

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:36', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '93030341-dd52-4290-aa72-f5edbe9a50e0' User entered '28 Sep 2020 07:52'	System	28 Sep 2020 12:52:37
	System	28 Sep 2020 12:52:37

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered 'None (1)'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered 'No (N)'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:26', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered 'No (N)'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered 'None (1)'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:42', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'cc6a3120-3fd7-47a0-97c8-a93dc96bf966'	System	21 Sep 2020 16:59:45
User entered '21 Sep 2020 11:59'	System	21 Sep 2020 16:59:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 14:10'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:47:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:02', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered 'No (N)'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered 'No (N)'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:43', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '3489aaeb-abaa-43bb-bf99-1552f9be6149'	System	22 Sep 2020 02:48:45
User entered '21 Sep 2020 21:48'	System	22 Sep 2020 02:48:45

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 15:05'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 2'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07'	System	23 Sep 2020 03:41:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:27', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07' User entered 'No (N)'	System	23 Sep 2020 03:41:52
	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:33', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07' User entered 'No (N)'	System	23 Sep 2020 03:41:52
	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:46', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07'	System	23 Sep 2020 03:41:52
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:41:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '364e9022-0048-4861-bec9-42ac3ab70b07'	System	23 Sep 2020 03:41:52
User entered '22 Sep 2020 22:41'	System	23 Sep 2020 03:41:52

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 3'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b'	System	24 Sep 2020 03:34:35
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:33:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b' User entered 'No (N)'	System	24 Sep 2020 03:34:35
	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b' User entered 'No (N)'	System	24 Sep 2020 03:34:35
	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:23', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b'	System	24 Sep 2020 03:34:35
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0d63097e-dcfb-498d-b589-b84542a6f30b' User entered '23 Sep 2020 22:34'	System	24 Sep 2020 03:34:35
	System	24 Sep 2020 03:34:35

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 4'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:46', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:51', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered 'No (N)'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:26:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered 'No (N)'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:01', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:05', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '680f6691-6619-4f9f-9f03-eaa9832b3fa7'	System	25 Sep 2020 03:27:10
User entered '24 Sep 2020 22:27'	System	25 Sep 2020 03:27:10

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 5'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 6'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:02', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:05', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered 'No (N)'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:08', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered 'No (N)'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:12', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b239fe1a-7b73-4aa5-abd5-11ea21cf3725'	System	26 Sep 2020 17:11:17
User entered '26 Sep 2020 12:11'	System	26 Sep 2020 17:11:17

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 7'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:41', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070'	System	28 Sep 2020 12:52:59
User entered 'None (1)'	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070' User entered 'No (N)'	System	28 Sep 2020 12:52:59
	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070' User entered 'No (N)'	System	28 Sep 2020 12:52:59
	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070'	System	28 Sep 2020 12:52:59
User entered 'None (1)'	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:52:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '399dddf8-9982-4585-b935-94fa99921070' User entered '28 Sep 2020 07:52'	System	28 Sep 2020 12:52:59
	System	28 Sep 2020 12:52:59

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:55', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T11:59:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39' User entered 'None (0)'	System	21 Sep 2020 17:00:20
	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'None (0)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:09', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered 'No (N)'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T12:00:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'df5485b9-bc47-43f2-b883-0cc05c0ccb39'	System	21 Sep 2020 17:00:20
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 17:00:20

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 14:10'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519' User entered 'None (0)'	System	22 Sep 2020 02:49:27
	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:48:58', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519' User entered 'None (0)'	System	22 Sep 2020 02:49:27
	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519' User entered 'None (0)'	System	22 Sep 2020 02:49:27
	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519' User entered 'None (0)'	System	22 Sep 2020 02:49:27
	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519' User entered 'None (0)'	System	22 Sep 2020 02:49:27
	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519' User entered 'None (0)'	System	22 Sep 2020 02:49:27
	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:20', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519' User entered 'No (N)'	System	22 Sep 2020 02:49:27
	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-21T21:49:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '13a72f1a-588d-42d3-874e-3375fb1c0519'	System	22 Sep 2020 02:49:27
User entered '21 Sep 2020 21:49'	System	22 Sep 2020 02:49:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '21 Sep 2020 15:05'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 2'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:11', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'Some interference with activity (2)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'Some interference with activity (2)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:31', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'No interference with activity (1)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797' User entered 'None (0)'	System	23 Sep 2020 03:43:00
	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:45', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797' User entered 'None (0)'	System	23 Sep 2020 03:43:00
	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered 'No (N)'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-22T22:42:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c85fefaa-61da-4c78-823b-bf63f09e9797'	System	23 Sep 2020 03:43:00
User entered '22 Sep 2020 22:42'	System	23 Sep 2020 03:43:00

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 3'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba' User entered 'None (0)'	System	24 Sep 2020 03:35:27
	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:34:50', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba' User entered 'Significant; prevents daily activity (3)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:02', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba'	System	24 Sep 2020 03:35:27
User entered 'Some interference with activity (2)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:07', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba'	System	24 Sep 2020 03:35:27
User entered 'Some interference with activity (2)'	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:12', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba' User entered 'None (0)'	System	24 Sep 2020 03:35:27
	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba' User entered 'None (0)'	System	24 Sep 2020 03:35:27
	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:20', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba' User entered 'No (N)'	System	24 Sep 2020 03:35:27
	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-23T22:35:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c3056c39-7d9c-4f90-9e72-72b3422299ba' User entered '23 Sep 2020 22:35'	System	24 Sep 2020 03:35:27
	System	24 Sep 2020 03:35:27

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 4'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:16', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'None (0)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb'	System	25 Sep 2020 03:27:46
User entered 'No interference with activity (1)'	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'No interference with activity (1)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'No interference with activity (1)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'None (0)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'None (0)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:41', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered 'No (N)'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-24T22:27:44', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7c6b7a18-1193-4844-8d4e-9fc71cd08adb' User entered '24 Sep 2020 22:27'	System	25 Sep 2020 03:27:46
	System	25 Sep 2020 03:27:46

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 5'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 6'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e' User entered 'None (0)'	System	26 Sep 2020 17:11:42
	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e'	System	26 Sep 2020 17:11:42
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e'	System	26 Sep 2020 17:11:42
User entered 'No interference with activity (1)'	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e' User entered 'None (0)'	System	26 Sep 2020 17:11:42
	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e' User entered 'None (0)'	System	26 Sep 2020 17:11:42
	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e' User entered 'None (0)'	System	26 Sep 2020 17:11:42
	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e' User entered 'No (N)'	System	26 Sep 2020 17:11:42
	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-26T12:11:37', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '5270c9f8-1f8e-4b17-98e6-d9b7d7913b2e' User entered '26 Sep 2020 12:11'	System	26 Sep 2020 17:11:42
	System	26 Sep 2020 17:11:42

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	21 Sep 2020 16:28:53
User entered 'Day 7'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:01', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:06', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'None (0)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered 'No (N)'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-09-28T07:53:24', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f80e09a4-cbbf-41e1-a4da-f84f934b734f' User entered '28 Sep 2020 07:53'	System	28 Sep 2020 12:53:26
	System	28 Sep 2020 12:53:26

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:28:53

US3442031

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:43:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:28:53

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:52:58

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:52:58

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:52:58

US3442031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:52:58

US3442031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 15:53:03

US3442031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	30 Sep 2020 15:53:03

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 23:18:40

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:18:40

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:18:40

US3442031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 23:18:40

US3442031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 23:18:45

US3442031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	05 Oct 2020 23:18:45

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:09

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:09

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:09

US3442031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 21:19:09

US3442031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 21:19:15

US3442031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	14 Oct 2020 21:19:15

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:29

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:29

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:29

US3442031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'VISIT3'	System	16 Oct 2020 15:19:29

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered empty.	System	16 Oct 2020 15:19:46

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24

US3442031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24

US3442031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:51

US3442031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:19:51

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:20:04

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:20:04

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '09:52'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:20:04

US3442031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '16 Oct 2020 09:52'	System	16 Oct 2020 15:20:04

US3442031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 15:20:10

US3442031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered '1'	System	16 Oct 2020 15:20:10

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 64'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-18T16:38:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0177fd21-15b9-4c63-b48e-dca93cb6e435'	System	18 Oct 2020 21:38:54
User entered 'No (N)'	System	18 Oct 2020 21:38:54

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-18T16:38:43', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0177fd21-15b9-4c63-b48e-dca93cb6e435'	System	18 Oct 2020 21:38:54
User entered 'No (N)'	System	18 Oct 2020 21:38:54

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-18T16:38:51', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '0177fd21-15b9-4c63-b48e-dca93cb6e435' User entered '18 Oct 2020 16:38:51'	System	18 Oct 2020 21:38:54
	System	18 Oct 2020 21:38:54

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 71'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-27T12:00:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7d3da2b5-77d8-461c-9f9e-7eb3bae531c5'	System	27 Oct 2020 17:02:00
User entered 'No (N)'	System	27 Oct 2020 17:02:00

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-27T12:00:54', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7d3da2b5-77d8-461c-9f9e-7eb3bae531c5'	System	27 Oct 2020 17:02:00
User entered 'No (N)'	System	27 Oct 2020 17:02:00

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-10-27T12:01:01', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '7d3da2b5-77d8-461c-9f9e-7eb3bae531c5' User entered '27 Oct 2020 12:01:01'	System	27 Oct 2020 17:02:00
	System	27 Oct 2020 17:02:00

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 78'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-01T10:57:10', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '51f0e67e-2e67-4ce1-9887-6082ed717e86'	System	01 Nov 2020 16:57:36
User entered 'No (N)'	System	01 Nov 2020 16:57:36

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-01T10:57:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '51f0e67e-2e67-4ce1-9887-6082ed717e86'	System	01 Nov 2020 16:57:36
User entered 'No (N)'	System	01 Nov 2020 16:57:36

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-01T10:57:30', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '51f0e67e-2e67-4ce1-9887-6082ed717e86' User entered '01 Nov 2020 10:57:30'	System	01 Nov 2020 16:57:36
	System	01 Nov 2020 16:57:36

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered 'Day 92'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-17T12:00:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a949e428-d1ca-4234-861f-ff5d97bad71b'	System	17 Nov 2020 18:00:59
User entered 'No (N)'	System	17 Nov 2020 18:00:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-17T12:00:47', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a949e428-d1ca-4234-861f-ff5d97bad71b'	System	17 Nov 2020 18:00:59
User entered 'No (N)'	System	17 Nov 2020 18:00:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-17T12:00:52', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a949e428-d1ca-4234-861f-ff5d97bad71b' User entered '17 Nov 2020 12:00:52'	System	17 Nov 2020 18:00:59
	System	17 Nov 2020 18:00:59

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 23:23:35

US3442031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:54:01
Data entry locked.	System	18 Aug 2020 23:23:35
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 23:23:35

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-26T09:17:03', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'd25607c4-98e8-4bca-816f-1680ea41b08f' User entered 'No (N)'	System	26 Nov 2020 15:17:33
	System	26 Nov 2020 15:17:33

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-26T09:17:23', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'd25607c4-98e8-4bca-816f-1680ea41b08f' User entered 'No (N)'	System	26 Nov 2020 15:17:33

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-11-26T09:17:29', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'd25607c4-98e8-4bca-816f-1680ea41b08f' User entered '26 Nov 2020 09:17:29'	System	26 Nov 2020 15:17:33
	System	26 Nov 2020 15:17:33

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-03T19:31:22', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '99c4bb40-139e-4f07-a28f-5ab8b5bda702' User entered 'No (N)'	System	04 Dec 2020 01:31:41

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-03T19:31:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '99c4bb40-139e-4f07-a28f-5ab8b5bda702'	System	04 Dec 2020 01:31:41
User entered 'No (N)'	System	04 Dec 2020 01:31:41

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-03T19:31:38', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '99c4bb40-139e-4f07-a28f-5ab8b5bda702' User entered '03 Dec 2020 19:31:38'	System	04 Dec 2020 01:31:41
	System	04 Dec 2020 01:31:41

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-14T18:38:48', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f0ae927a-5a6a-493f-91b4-931021749379'	System	14 Dec 2020 23:39:00
User entered 'No (N)'	System	14 Dec 2020 23:39:00

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-14T18:38:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f0ae927a-5a6a-493f-91b4-931021749379' User entered 'No (N)'	System	14 Dec 2020 23:39:00
	System	14 Dec 2020 23:39:00

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-14T18:38:57', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f0ae927a-5a6a-493f-91b4-931021749379' User entered '14 Dec 2020 18:38:57'	System	14 Dec 2020 23:39:00
	System	14 Dec 2020 23:39:00

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-17T07:12:43', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8e295b19-b0f6-4ad4-8350-a80127841a0b' User entered 'No (N)'	System	17 Dec 2020 12:13:06
	System	17 Dec 2020 12:13:06

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-17T07:12:54', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8e295b19-b0f6-4ad4-8350-a80127841a0b' User entered 'No (N)'	System	17 Dec 2020 12:13:06
	System	17 Dec 2020 12:13:06

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-17T07:13:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8e295b19-b0f6-4ad4-8350-a80127841a0b' User entered '17 Dec 2020 07:13:00'	System	17 Dec 2020 12:13:06
	System	17 Dec 2020 12:13:06

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-27T18:00:27', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9f628468-9c8b-4047-8e75-41b09a8a1889'	System	28 Dec 2020 00:00:55
User entered 'No (N)'	System	28 Dec 2020 00:00:55

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-27T18:00:39', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9f628468-9c8b-4047-8e75-41b09a8a1889'	System	28 Dec 2020 00:00:55
User entered 'No (N)'	System	28 Dec 2020 00:00:55

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2020-12-27T18:00:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '9f628468-9c8b-4047-8e75-41b09a8a1889'	System	28 Dec 2020 00:00:55
User entered '27 Dec 2020 18:00:53'	System	28 Dec 2020 00:00:55

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-02T15:54:28', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '390377b0-9020-4ea3-9213-b415c0867f00'	System	02 Jan 2021 21:54:37
User entered 'No (N)'	System	02 Jan 2021 21:54:37

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-02T15:54:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '390377b0-9020-4ea3-9213-b415c0867f00'	System	02 Jan 2021 21:54:37
User entered 'No (N)'	System	02 Jan 2021 21:54:37

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-02T15:54:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '390377b0-9020-4ea3-9213-b415c0867f00'	System	02 Jan 2021 21:54:37
User entered '02 Jan 2021 15:54:35'	System	02 Jan 2021 21:54:37

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-07T06:39:32', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '47dec4bd-c061-4321-9b19-89215b4e6785'	System	07 Jan 2021 12:39:42
User entered 'No (N)'	System	07 Jan 2021 12:39:42

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-07T06:39:35', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '47dec4bd-c061-4321-9b19-89215b4e6785'	System	07 Jan 2021 12:39:42
User entered 'No (N)'	System	07 Jan 2021 12:39:42

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-07T06:39:40', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '47dec4bd-c061-4321-9b19-89215b4e6785'	System	07 Jan 2021 12:39:42
User entered '07 Jan 2021 06:39:40'	System	07 Jan 2021 12:39:42

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-15T11:42:25', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a3ffeff1-bd3f-4632-9e08-b1e014a82298'	System	15 Jan 2021 17:42:37
User entered 'No (N)'	System	15 Jan 2021 17:42:37

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-15T11:42:29', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a3ffeff1-bd3f-4632-9e08-b1e014a82298'	System	15 Jan 2021 17:42:37
User entered 'No (N)'	System	15 Jan 2021 17:42:37

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-15T11:42:33', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'a3ffeff1-bd3f-4632-9e08-b1e014a82298' User entered '15 Jan 2021 11:42:33'	System	15 Jan 2021 17:42:37

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-23T13:02:11', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c7d5bd64-14c6-4221-967f-47036f520bc7' User entered 'No (N)'	System	23 Jan 2021 21:02:24
	System	23 Jan 2021 21:02:24

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-23T13:02:15', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c7d5bd64-14c6-4221-967f-47036f520bc7'	System	23 Jan 2021 21:02:24
User entered 'No (N)'	System	23 Jan 2021 21:02:24

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-23T13:02:19', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c7d5bd64-14c6-4221-967f-47036f520bc7' User entered '23 Jan 2021 13:02:19'	System	23 Jan 2021 21:02:24
	System	23 Jan 2021 21:02:24

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-30T22:37:09', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '20acaf1b-71f7-4fcf-93de-d620ad9332d5'	System	31 Jan 2021 04:37:20
User entered 'No (N)'	System	31 Jan 2021 04:37:20

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-30T22:37:13', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '20acaf1b-71f7-4fcf-93de-d620ad9332d5'	System	31 Jan 2021 04:37:20
User entered 'No (N)'	System	31 Jan 2021 04:37:20

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-01-30T22:37:17', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '20acaf1b-71f7-4fcf-93de-d620ad9332d5' User entered '30 Jan 2021 22:37:17'	System	31 Jan 2021 04:37:20
	System	31 Jan 2021 04:37:20

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-07T11:08:53', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '94e898ef-3465-4454-9ea3-104395c1e581' User entered 'No (N)'	System	07 Feb 2021 17:10:12
	System	07 Feb 2021 17:10:12

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-07T11:08:56', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '94e898ef-3465-4454-9ea3-104395c1e581' User entered 'No (N)'	System	07 Feb 2021 17:10:12
	System	07 Feb 2021 17:10:12

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-07T11:08:59', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '94e898ef-3465-4454-9ea3-104395c1e581' User entered '07 Feb 2021 11:08:59'	System	07 Feb 2021 17:10:12
	System	07 Feb 2021 17:10:12

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-13T12:01:33', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1043fb50-5790-4efd-b25d-68c146d75a17'	System	13 Feb 2021 17:06:52
User entered 'No (N)'	System	13 Feb 2021 17:06:52

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-13T12:01:39', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1043fb50-5790-4efd-b25d-68c146d75a17'	System	13 Feb 2021 17:06:52
User entered 'No (N)'	System	13 Feb 2021 17:06:52

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-13T12:01:49', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1043fb50-5790-4efd-b25d-68c146d75a17'	System	13 Feb 2021 17:06:52
User entered '13 Feb 2021 12:01:49'	System	13 Feb 2021 17:06:52

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-20T14:20:14', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4ce1201a-2bfd-4187-9cee-abfec98fe0fc' User entered 'No (N)'	System	20 Feb 2021 21:20:27
	System	20 Feb 2021 21:20:27

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-20T14:20:18', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4ce1201a-2bfd-4187-9cee-abfec98fe0fc' User entered 'No (N)'	System	20 Feb 2021 21:20:27

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-20T14:20:21', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4ce1201a-2bfd-4187-9cee-abfec98fe0fc' User entered '20 Feb 2021 14:20:21'	System	20 Feb 2021 21:20:27
	System	20 Feb 2021 21:20:27

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-27T12:08:04-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b2b5739d-9c1e-4403-abb2-e1318c09f5d9' User entered 'No (N)'	System	27 Feb 2021 18:12:15
	System	27 Feb 2021 18:12:15

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-27T12:08:07-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b2b5739d-9c1e-4403-abb2-e1318c09f5d9' User entered 'No (N)'	System	27 Feb 2021 18:12:15
	System	27 Feb 2021 18:12:15

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-27T12:08:12-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'b2b5739d-9c1e-4403-abb2-e1318c09f5d9' User entered '27 Feb 2021 18:08:12'	System	27 Feb 2021 18:12:15
	System	27 Feb 2021 18:12:15

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-04T08:50:48-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c620e48e-7e04-41fb-8415-37724a0e9c8e'	System	04 Mar 2021 14:51:18
User entered 'No (N)'	System	04 Mar 2021 14:51:18

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-04T08:50:54-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c620e48e-7e04-41fb-8415-37724a0e9c8e'	System	04 Mar 2021 14:51:18
User entered 'No (N)'	System	04 Mar 2021 14:51:18

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-04T08:50:57-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'c620e48e-7e04-41fb-8415-37724a0e9c8e' User entered '04 Mar 2021 08:50:57'	System	04 Mar 2021 14:51:18
	System	04 Mar 2021 14:51:18

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-11T10:07:40-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4e70e2d6-062e-425c-9a94-6a0fed62d2c9' User entered 'No (N)'	System	11 Mar 2021 15:07:51
	System	11 Mar 2021 15:07:51

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-11T10:07:43-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4e70e2d6-062e-425c-9a94-6a0fed62d2c9'	System	11 Mar 2021 15:07:51
User entered 'No (N)'	System	11 Mar 2021 15:07:51

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-11T10:07:48-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '4e70e2d6-062e-425c-9a94-6a0fed62d2c9' User entered '11 Mar 2021 10:07:48'	System	11 Mar 2021 15:07:51
	System	11 Mar 2021 15:07:51

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-22T12:07:26-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bfe8a081-239c-44ba-92b3-13f08fbef03c'	System	22 Mar 2021 17:20:59
User entered 'No (N)'	System	22 Mar 2021 17:20:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-22T12:07:30-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bfe8a081-239c-44ba-92b3-13f08fbef03c'	System	22 Mar 2021 17:20:59
User entered 'No (N)'	System	22 Mar 2021 17:20:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-22T12:07:33-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'bfe8a081-239c-44ba-92b3-13f08fbef03c'	System	22 Mar 2021 17:20:59
User entered '22 Mar 2021 12:07:33'	System	22 Mar 2021 17:20:59

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-29T12:00:45-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6f0e975e-b30a-498f-8b07-c0b9d2cca7c7'	System	29 Mar 2021 17:01:43
User entered 'No (N)'	System	29 Mar 2021 17:01:43

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-29T12:00:48-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6f0e975e-b30a-498f-8b07-c0b9d2cca7c7'	System	29 Mar 2021 17:01:43
User entered 'No (N)'	System	29 Mar 2021 17:01:43

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-03-29T12:00:51-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '6f0e975e-b30a-498f-8b07-c0b9d2cca7c7' User entered '29 Mar 2021 12:00:51'	System	29 Mar 2021 17:01:43
	System	29 Mar 2021 17:01:43

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-03T12:17:51-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'd9ffbefd-554e-4707-9697-5c900d8f731e' User entered 'No (N)'	System	03 Apr 2021 17:18:01
	System	03 Apr 2021 17:18:01

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-03T12:17:54-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'd9ffbefd-554e-4707-9697-5c900d8f731e'	System	03 Apr 2021 17:18:01
User entered 'No (N)'	System	03 Apr 2021 17:18:01

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-03T12:17:57-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'd9ffbefd-554e-4707-9697-5c900d8f731e'	System	03 Apr 2021 17:18:01
User entered '03 Apr 2021 12:17:57'	System	03 Apr 2021 17:18:01

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-08T20:15:20-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'e77842c0-9894-4040-b280-d698dab91902'	System	09 Apr 2021 02:16:15
User entered 'No (N)'	System	09 Apr 2021 02:16:15

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-08T20:15:27-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'e77842c0-9894-4040-b280-d698dab91902'	System	09 Apr 2021 02:16:15
User entered 'No (N)'	System	09 Apr 2021 02:16:15

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-08T20:16:10-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'e77842c0-9894-4040-b280-d698dab91902'	System	09 Apr 2021 02:16:15
User entered '08 Apr 2021 20:16:10'	System	09 Apr 2021 02:16:15

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-18T19:21:54-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f20b3bed-2125-413b-a251-0bd0569952e1' User entered 'No (N)'	System	19 Apr 2021 00:22:08
	System	19 Apr 2021 00:22:08

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-18T19:21:59-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f20b3bed-2125-413b-a251-0bd0569952e1' User entered 'No (N)'	System	19 Apr 2021 00:22:08
	System	19 Apr 2021 00:22:08

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-18T19:22:03-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: 'f20b3bed-2125-413b-a251-0bd0569952e1' User entered '18 Apr 2021 19:22:03'	System	19 Apr 2021 00:22:08
	System	19 Apr 2021 00:22:08

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-22T08:37:53-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1df181b8-049d-49c9-9e6a-1873f398c3a7'	System	22 Apr 2021 13:38:12
User entered 'No (N)'	System	22 Apr 2021 13:38:12

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-22T08:38:03-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1df181b8-049d-49c9-9e6a-1873f398c3a7'	System	22 Apr 2021 13:38:12
User entered 'No (N)'	System	22 Apr 2021 13:38:12

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-04-22T08:38:08-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '1df181b8-049d-49c9-9e6a-1873f398c3a7'	System	22 Apr 2021 13:38:12
User entered '22 Apr 2021 08:38:08'	System	22 Apr 2021 13:38:12

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-05-03T22:24:22-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8d09e824-30d4-40dc-b7c1-376712c1bb59'	System	04 May 2021 03:24:33
User entered 'No (N)'	System	04 May 2021 03:24:33

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

Have you been exposed to someone with 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 (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-05-03T22:24:27-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8d09e824-30d4-40dc-b7c1-376712c1bb59'	System	04 May 2021 03:24:33
User entered 'No (N)'	System	04 May 2021 03:24:33

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-05-03T22:24:30-05:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '8d09e824-30d4-40dc-b7c1-376712c1bb59'	System	04 May 2021 03:24:33
User entered '03 May 2021 22:24:30'	System	04 May 2021 03:24:33

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:38:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:38:31

US3442031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:43:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:38:31
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:38:31

US3442031

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:43:19

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 07:45:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-27T12:08:36-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '76c37ec0-0e2e-49ef-89d9-1e266939b687'	System	04 Mar 2021 14:51:17
User entered 'No (N)'	System	04 Mar 2021 14:51:17

US3442031

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:43:19

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:45:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4A81CC5A-6B66-4C44-8EA5-02AB54CC5FEA)', Time: '2021-02-27T12:08:40-06:00', User OID: 'PatientReportedOutcome (US3442031)', ODM File OID: '76c37ec0-0e2e-49ef-89d9-1e266939b687'	System	04 Mar 2021 14:51:17
User entered '27 Feb 2021 18:08:40'	System	04 Mar 2021 14:51:17

US3442031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:20

US3442031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '13 Nov 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:20

US3442031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:20

US3442031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:20

US3442031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:28

US3442031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 05:11:24
User entered 'I'	System	07 Dec 2020 22:03:28

US3442031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:43

US3442031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '7 Dec 2020'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:43

US3442031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:43

US3442031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:43

US3442031

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:03:57

US3442031

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User entered 'I'	System	07 Dec 2020 22:03:57

US3442031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 00:48:53

US3442031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '20 Jan 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 00:48:53

US3442031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 00:48:53

US3442031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 00:48:53

US3442031

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	21 Jan 2021 00:49:01

US3442031

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User entered 'I'	System	21 Jan 2021 00:49:01

US3442031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:34:03

US3442031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:26
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:27:49
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct as entered' (Site from System).		24 Feb 2021 16:34:12
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Feb 2021 16:34:03
User entered '22 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 16:34:03

US3442031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:34:03

US3442031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:43:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:26
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 16:34:03

US3442031

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:34:19

US3442031

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:34:26
User entered 'I'	System	24 Feb 2021 16:34:19

US3442031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:10:49

US3442031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered '8 Mar 2021'	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:10:49

US3442031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[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 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered 'Clinic (Clinic)'	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:10:49

US3442031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'VISIT4'	System	19 Mar 2021 21:10:49

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered 'No (N)'	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Apr 2021 15:17:05
User entered empty.	John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) John Villegas (b) (4) (b) (4)	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered empty.	System	30 Mar 2021 18:33:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26

US3442031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:43:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26

US3442031

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered 'No (N)'	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:11:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:43:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered empty.	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:11:04

US3442031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:11:26

US3442031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 08MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' (Site from DM). Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 08MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' answered with 'PPD has been made a wear of this, Site did not have Visit 4 Lab kits so unscheduled lab kits have been used' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 12:29:03
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 08MAR2021 is recorded under Visit 04 Day 209 Visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' (Site from DM). User entered '8 Mar 2021'	John Villegas (b) (4)	26 Mar 2021 14:47:35
	(b) (4)	
	(b) (4), (b) (6)	26 Mar 2021 04:18:07
	Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:11:26

US3442031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered '12:18'	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:11:26

US3442031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered '8 Mar 2021 12:18'	System	19 Mar 2021 21:11:26

US3442031

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User entered 'Yes (Y)'	(b) (4) Oluwatosin Akingbala (b) (4)	19 Mar 2021 21:11:35

US3442031

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:43:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:26
User entered 'I'	System	19 Mar 2021 21:11:35

US3442031

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:07:41

US3442031

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 18:52:00
User entered '5 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 18:07:41

US3442031

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[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 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:07:41

US3442031

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

Form: Visit Date

Generated On: 09 Jun 2021 17:43:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 18:07:41

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Feb 2021 18:52:17
User entered '5 Jan 2021'		05 Jan 2021 18:07:59

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[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 17:06:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:26
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:41:37

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:07:59

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	18 Mar 2021 21:26:26
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 05:41:37

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 18:52:17
User entered '5 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 18:07:59

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:07:59

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 02:39:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	05 Jan 2021 18:07:59

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 02:39:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	05 Jan 2021 18:07:59

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:07:59

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User entered empty.	System	05 Jan 2021 18:07:59

US3442031

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

Form: Unblinding

Generated On: 09 Jun 2021 17:43:19

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User entered empty.	System	05 Jan 2021 18:07:59

US3442031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:08:21

US3442031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 04Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:17:30
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 04Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'data entry error. 04Jan2021 is the correct sample collection date' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 18:53:26
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 18:52:43
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	09 Feb 2021 18:52:43
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:52:43
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 18:52:00
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 05Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 04Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 17:32:17

US3442031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 18:08:21

US3442031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '09:51'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:08:21

US3442031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:43:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User entered '4 Jan 2021 09:51'	System	09 Feb 2021 18:52:43
User entered '5 Jan 2021 09:51'	System	05 Jan 2021 18:08:21

US3442031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:08:35

US3442031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "05-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "04-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 10:11:20
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "05-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "04-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' answered with 'correct date updated' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 18:54:16
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 18:54:05
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "05-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "04-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).		08 Feb 2021 10:55:14
User entered '5 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 18:08:35

US3442031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '09:52'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:08:35

US3442031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:43:19

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:06:35
User entered '4 Jan 2021 09:52'	System	09 Feb 2021 18:54:05
User entered '5 Jan 2021 09:52'	System	05 Jan 2021 18:08:35

US3442031

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:43:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:42
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:28:56
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:49:48

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:00
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site warmth, LLT: Injection site warmth - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:24:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 20:24:42
Data point term sent to Coder	System	28 Aug 2020 19:51:40
User entered 'HEAT AT INJECTION SITE'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:02
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:04
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:20
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:25
User entered '26 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:26
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	28 Aug 2020 19:51:48
User entered empty; reason for change Data Entry Error	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:48
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	28 Aug 2020 19:51:21
User entered '00:00'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered empty.	System	28 Aug 2020 19:51:48
User entered '26 Aug 2020 00:00'	System	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 04:23:27
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	09 Dec 2020 19:42:32
DataPoint Un-verified.	Alma Guel (b) (4)	09 Dec 2020 19:42:20
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 19:42:20
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 09:36:33
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:16:28
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
DataPoint Un-verified.	Alma Guel (b) (4)	09 Dec 2020 19:42:20
User entered '29 Aug 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 19:42:20
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:16:36
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:37
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered empty.	System	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:41
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:46
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:47
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:48
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).		28 Aug 2020 19:52:09
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).		28 Aug 2020 19:52:09
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	28 Aug 2020 19:51:21
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:50
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:51
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:53
User entered empty; reason for change Data Entry Error	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:52:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:54
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

US3442031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:55
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:57
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:16:58
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:17:01
User entered 'Related (RELATED)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:17:03
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).		19 Nov 2020 20:07:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	18 Nov 2020 22:01:58
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.	John Villegas (b) (4) (b) (4)	18 Nov 2020 22:01:52
' answered with 'Per Sub-I, heat at injection site is a causality to IP, not to the study procedure itself' (Site from DM).		
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:11:28
User entered 'Not Applicable (NOT APPLICABLE)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:17:06
User entered 'None (NONE)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:17:29
User entered 'l'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:17:31
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:21:49
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Un-verified.	(b) (4)	
User entered 'Recovered/Resolved	Alma Guel (b) (4)	09 Dec 2020 19:42:20
(RECOVERED/RESOLVED)' reason for change:	Alma Guel (b) (4)	09 Dec 2020 19:42:20
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:21:50
User entered 'Not Recovered/Not Resolved (NOT	Melody Dufrene (b) (4)	28 Aug 2020 19:51:21
RECOVERED/NOT RESOLVED)'	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:21:55
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:21:56
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered '0'	System	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:43:19

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered '0'	System	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:35:57
User entered '0'	System	28 Aug 2020 19:51:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 13:08:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 13:08:04
User closed query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and the specific location and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 04:40:10
Data point term sent to Coder	System	03 Dec 2020 16:31:07
Query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and the specific location and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'updated accordingly' (Site from DM).	Alma Guel (b) (4)	03 Dec 2020 16:30:53
DataPoint Un-verified.	Alma Guel (b) (4)	03 Dec 2020 16:30:41
Coding entries removed.	Alma Guel (b) (4)	03 Dec 2020 16:30:41
User entered 'Lymphadenopathy RIGHT AXILLA- IPSILATERAL TO VACCINATION SITE' reason for change: Data Entry Error	Alma Guel (b) (4)	03 Dec 2020 16:30:41
User opened query 'Per DM CLR: Please review if this AE is considered as Lymphadenopathy. If yes, please update to record Lymphadenopathy and the specific location and indicate whether this is Ipsilateral or Contralateral to Injection Site. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 11:12:17
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:25:01

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EAB) (1725)

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[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:02:26
User closed query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:02:16
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Vaccination site reactions, PT: Vaccination site lymphadenopathy, LLT: Vaccination site lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 13:02:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 13:02:32
Data point term sent to Coder	System	04 Nov 2020 21:55:52
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.	(b) (4), (b) (6)	04 Nov 2020 21:55:45
' answered with 'updated' (Site from DM).		
Coding entries removed.		04 Nov 2020 21:55:18
User entered 'SWOLLEN LYMPH NODES RIGHT AXILLA- ipsilateral to vaccination site' reason for change: Data Entry Error		04 Nov 2020 21:55:18
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.		02 Nov 2020 02:20:23
' (Site from DM).		

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Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy.' answered with 'correct as entered. subject does not have lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:35:55
User opened query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:52:07
User closed query 'Per DM CLR: Please specify the location of SWOLLEN LYMPH NODES (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:17:06
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Axillary lymph nodes enlarged - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 20:55:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 20:55:49
Data point term sent to Coder	System	08 Oct 2020 14:17:35
Query 'Per DM CLR: Please specify the location of SWOLLEN LYMPH NODES (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:16:58
Coding entries removed.	(b) (4), (b) (6)	08 Oct 2020 14:16:48
User entered 'SWOLLEN LYMPH NODES right axilla' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:16:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location of SWOLLEN LYMPH NODES (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:37:38
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Swollen lymph nodes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:55:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 19:55:46
Data point term sent to Coder	System	28 Aug 2020 19:54:45
User entered 'SWOLLEN LYMPH NODES'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:15
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:19
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:21
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:24
User entered '26 Aug 2020'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:25
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User entered empty.	System	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 04:23:34
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	09 Dec 2020 19:43:22
DataPoint Un-verified.	Alma Guel (b) (4)	09 Dec 2020 19:43:14
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 19:43:14
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 09:36:44
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:25:27
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Un-verified.	(b) (4)	
	Alma Guel (b) (4)	09 Dec 2020 19:43:14
User entered '29 Aug 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 19:43:14
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:25:32
User entered empty.	Melody Dufrene (b) (4)	28 Aug 2020 19:54:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:33
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User entered empty.	System	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:39
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:40
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:42
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:44
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:45
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:47
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:49
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:50
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:52
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

US3442031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:53
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:54
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:56
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:55:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:55:09
User entered 'Related (RELATED)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:55:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:54:32
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:58
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:55:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:55:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:55:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:54:32
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:25:59
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:55:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:55:09
User entered 'None (NONE)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:55:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:54:32
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:26:01
User entered '1' reason for change: Data Entry Error		08 Oct 2020 14:16:48
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:26:07
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		14 Oct 2020 12:17:14
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:17:05
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:16:48
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		02 Oct 2020 02:32:03
User entered '1'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:26:09
User entered '0'	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
DataPoint Un-verified.	Alma Guel (b) (4)	09 Dec 2020 19:43:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Alma Guel (b) (4)	09 Dec 2020 19:43:14
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 17:26:11
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:55:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Aug 2020 19:55:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:55:15
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 19:54:32
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:26:13
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:26:15
User entered empty.	Melody Dufrene (b) (4) (b) (4)	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:43:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User entered '0'	System	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01
User entered '0'	System	28 Aug 2020 19:54:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:36:01

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:51:25
Reviewed for Safety.		09 Nov 2020 18:01:50
User entered		09 Nov 2020 18:01:41
'USA-US017-2020-mRNA-1273-P301000003'		
User entered 'New'		09 Nov 2020 18:01:41

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:27:15
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:08:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 00:08:36
Data point term sent to Coder	System	13 Nov 2020 17:36:06
DataPoint Un-verified.	Alma Guel (b) (4)	13 Nov 2020 17:35:43
Coding entries removed.	Alma Guel (b) (4)	13 Nov 2020 17:35:43
User entered 'DEEP VEIN THROMBOSIS (Left Leg)' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:35:43
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:51:27
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:26:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:26:33
Data point term sent to Coder	System	06 Nov 2020 21:25:16
User entered 'Deep Vein Thrombosis'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:45
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:46
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:48
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:52
User entered '3 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:53
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:55
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:53:57
User entered '4 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 20:39:59
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:00
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:26:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 21:26:19
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Alma Guel (b) (4)	06 Nov 2020 21:26:19
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 21:25:01
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:03
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:05
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:07
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:16
User entered 'I'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:28
User entered '3 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:46
User entered '4 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:48
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:50
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:51
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:53
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:54
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:56
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:57
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:54:59
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:24:27
User closed query 'Subject is received medications after the diagnosis. Please check the concomitant Medication option. ' (Site from CRA).		19 Nov 2020 17:23:52
Query 'Subject is received medications after the diagnosis. Please check the concomitant Medication option. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	13 Nov 2020 17:06:18
User entered '0' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:06:10
User opened query 'Subject is received medications after the diagnosis. Please check the concomitant Medication option. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:02:49
User entered '1'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 04:24:47
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'Left calf pain (secondary to deep vein thrombosis) updated' (Site from DM).	Alma Guel (b) (4)	09 Dec 2020 19:48:21
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 11:03:51
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:24:45
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:06:10
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:24:48
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:02:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:02:56
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:03
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Nov 2020 21:26:01
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	06 Nov 2020 21:26:01
User entered 'Subject hospitalized overnight for deep Alma Guel vein thrombosis. Subject was released and medical records have been requested.' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 21:26:01
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Nov 2020 21:25:01
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:43:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 21:25:01

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4)	12 Nov 2020 18:03:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:02:15
User entered 'USA-US017-2020-mRNA-1273-P301000003'		09 Nov 2020 18:02:10

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:44:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:44:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:29:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:29:24
Data point term sent to Coder	System	06 Nov 2020 21:28:22
User entered 'Pulmonary Embolism'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:13
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:15
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:17
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:19
User entered '3 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:21
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:23
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:25
User entered '4 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:28
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:31
User entered 'Yes (Y)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:34
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:36
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:38
User entered 'I'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:40
User entered '3 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:41
User entered '4 Nov 2020'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:43
User entered 'No (N)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:45
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:47
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:49
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:51
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:53
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:54
User entered 'Not Related (NOT RELATED)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:03:56
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

US3442031

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

None

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:26:56
User closed query 'Subject is taking medications related to the condition. Please check the option of concomitant medication. ' (Site from CRA).		19 Nov 2020 17:26:46
Query 'Subject is taking medications related to the condition. Please check the option of concomitant medication. ' answered with 'data updated' (Site from CRA).	Alma Guel (b) (4)	13 Nov 2020 17:34:55
User entered '0' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:34:44
User opened query 'Subject is taking medications related to the condition. Please check the option of concomitant medication. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 18:04:42
DataPoint Un-verified.		12 Nov 2020 18:04:00
DataPoint Verified.		12 Nov 2020 18:03:58
User entered '1'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (u) (4), (b) (6)	10 Dec 2020 04:28:00
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	09 Dec 2020 19:50:48
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 11:04:41
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:58
User entered '1' reason for change: Data Entry Error	Alma Guel (b) (4)	13 Nov 2020 17:34:44
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:27:01
User entered '0'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:04:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alma Guel (b) (4)	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:04:50
User entered empty.	Alma Guel (b) (4)	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:33:49
User closed query 'PV Query: Please provide clinical work-ups for thrombophilia.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 19:33:47
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)	10 Dec 2020 19:33:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 19:33:44
User closed query 'PV Query: Please provide treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 19:33:42
Query 'PV Query: Please provide clinical work-ups for thrombophilia.' answered with 'self reported by subject during screening' (Site from Safety).	Alma Guel (b) (4)	09 Dec 2020 20:16:19
Query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. ' answered with 'no' (Site from Safety).	Alma Guel (b) (4)	09 Dec 2020 19:53:44
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' (Site from Safety).	Alma Guel (b) (4)	09 Dec 2020 19:52:54

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Narrative](#)

Audit	User		Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'provided' (Site from Safety).	Alma Guel	(b) (4)	09 Dec 2020 19:52:47
Query 'PV Query: Please provide treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Alma Guel	(b) (4)	09 Dec 2020 19:52:21
User opened query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results.'	(b) (4), (b) (6)		13 Nov 2020 17:44:53
' (Site from Safety).			
User opened query 'PV Query: Please provide clinical work-ups for thrombophilia.' (Site from Safety).	(b) (4), (b) (6)		13 Nov 2020 17:40:33
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).			13 Nov 2020 17:39:39
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)		13 Nov 2020 17:39:29
User opened query 'PV Query: Please provide treatment given for the events including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).			13 Nov 2020 17:38:37
DataPoint Verified.	(b) (4), (b) (6)		12 Nov 2020 18:04:52
User entered 'SUBJECT HOSPITALIZED OVERNIGHT FOR Pulmonary Embolism. SUBJECT WAS RELEASED AND MEDICAL RECORDS HAVE BEEN REQUESTED'	Alma Guel	(b) (4)	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:43:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 21:28:05

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:56:09
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Solicited symptom lasting longer than the first 7 days are considered AE's per protocol. ' (Site from DM).	John Villegas (b) (4) (b) (4)	14 Dec 2020 20:58:49
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 16:48:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:34:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 16:34:51
Data point term sent to Coder	System	14 Nov 2020 16:34:18
User entered 'Shortness of breath'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '4 Nov 2020'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User entered empty.	System	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '12 Nov 2020'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User entered empty.	System	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'No (N)'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

US3442031

Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Form: Adverse Events (7)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:16:30
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	23 Nov 2020 20:58:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Nov 2020 20:58:21
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:11:05
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	Alma Guel (b) (4)	23 Nov 2020 20:58:21
User entered 'Not Applicable (NOT APPLICABLE)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:16:32
User entered 'Not Applicable (NOT APPLICABLE)' Alma Guel reason for change: Data Entry Error	(b) (4)	23 Nov 2020 20:58:48
Query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	23 Nov 2020 20:58:36
User opened query 'Per CDM: Action taken with IP should be recorded as NOT APPLICABLE if the AE started after the second dose. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 10:52:56
User entered 'None (NONE)'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '0'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per DM CLR: RQ: Response noted, however, Chest X-Ray does not treat this medical condition and it is only used for diagnostic purposes. Review and update the response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: RQ: Response noted, however, Chest X-Ray does not treat this medical condition and it is only used for diagnostic purposes. Review and update the response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 15:12:13
Query 'Per DM CLR: RQ: Response noted, however, Chest X-Ray does not treat this medical condition and it is only used for diagnostic purposes. Review and update the response as appropriate. Otherwise, clarify.' answered with 'Shortness of breath is due to the pulmonary embolism. Con Med log has been updated to reflect.' (Site from DM).	Tisha Davis (b) (4)	26 Jan 2021 16:35:03
User opened query 'Per DM CLR: RQ: Response noted, however, Chest X-Ray does not treat this medical condition and it is only used for diagnostic purposes. Review and update the response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: RQ: Response noted, however, Chest X-Ray does not treat this medical condition and it is only used for diagnostic purposes. Review and update the response as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 07:14:09
User opened query 'Per DM CLR: RQ: Response noted, however, Chest X-Ray does not treat this medical condition and it is only used for diagnostic purposes. Review and update the response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 07:14:02
User closed query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.	(b) (4), (b) (6)	13 Jan 2021 07:13:45
' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 15:56:02

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Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'Per Medical records, Chest X-ray was preformed due to subject complaining of Shortness of breath. This is usually done to rule out pneumonia and other heart or lung problems' (Site from DM).	John Villegas (b) (4)	14 Dec 2020 14:27:31
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:13:38
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:13:38
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'updated Chest x-ray in con procedures to reflect Shortness of Breath' (Site from DM).	Alma Guel (b) (4)	09 Dec 2020 20:18:49
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 11:11:19
User entered 'I'	Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Form: Adverse Events (7)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered empty.	(b) (4) Alma Guel (b) (4)	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User entered '0'	System	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19
User entered 'I'	System	14 Nov 2020 16:33:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:37:19

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Folder: Adverse Events

Form: Adverse Events (8)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00

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Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:46:36
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:58:01
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 22:58:01
Data point term sent to Coder	System	19 Nov 2020 22:57:01
User entered 'Nausea'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:46:38
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:46:39
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:46:40
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:46:51
User entered '26 Aug 2020'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:46:57
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Form: Adverse Events (8)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User entered empty.	System	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:46:59
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:00
User entered '27 Aug 2020'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:01
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User entered empty.	System	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:05
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:06
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:08
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:09
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Nov 2020 22:57:04
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	19 Nov 2020 22:57:04
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	19 Nov 2020 22:56:44
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Generated On: 09 Jun 2021 17:43:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:10
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:12
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:13
User entered empty; reason for change Data Entry Error	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:57:04
User entered 'No (N)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:15
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:16
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:17
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:19
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:21
User entered 'Related (RELATED)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:22
User entered 'Not Related (NOT RELATED)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:23
User entered 'None (NONE)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:25
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:27
User entered 'l'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:28
User entered '0'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:33
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:47:32
User entered empty.	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User entered '0'	System	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User entered '0'	System	19 Nov 2020 22:56:44

US3442031

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:43:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:51:00
User entered '0'	System	19 Nov 2020 22:56:44

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:42
DataPoint Verified.		14 Apr 2021 19:04:18
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Pain at Injection Site; Headache (General) = 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).		23 Feb 2021 16:32:11
Query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Pain at Injection Site; Headache (General) = 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 'corresponding medication recorded in con med. subject took Tylenol. 22sep2020 through 24sep2020 for elevated temperature, body aches, and fatigue.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 18:27:26
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Pain at Injection Site; Headache (General) = 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 17:41:53
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 14:22:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 14:22:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 14:21:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 14:21:29
Data point term sent to Coder Query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' canceled (Site from System).	System Coder Import (b) (4) (b) (4)	01 Sep 2020 14:21:20 01 Sep 2020 14:20:39
Data point term sent to Coder User entered 'PROTONIX (pantoprazole)' reason for change: Per Query Resolution	System (b) (4), (b) (6)	01 Sep 2020 14:20:18 01 Sep 2020 14:19:28

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).	Coder Import (b) (4)	01 Sep 2020 07:42:41
Data point term sent to Coder	System	25 Aug 2020 15:25:49
User entered 'PROTONIX'	Melody Dufrene (b) (4)	25 Aug 2020 15:25:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:43
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:45
User entered 'ACID REFLUX'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Feb 2021 18:51:46
Signature has been broken.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:18:20
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:46
User entered '20'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:52
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:54
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 21:30:52
DataPoint Un-verified.	Alma Guel (b) (4)	04 Dec 2020 18:08:38
User entered 'as needed (PRN)' reason for change:	Alma Guel (b) (4)	04 Dec 2020 18:08:38
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:28:55
User entered 'once daily (QD)'	Melody Dufrene (b) (4)	25 Aug 2020 15:25:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:56
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:57
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:28:59
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:29:01
User entered 'UN UNK 2016'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:29:03
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:29:04
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:29:07
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:29:09
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 18:08:38
User entered '1'	System	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 18:08:38
User entered '1'	System	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 18:08:38
User entered '804 (804)'	System	25 Aug 2020 15:25:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:27
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)	13 Nov 2020 17:38:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:38:46
Data point term sent to Coder	System	13 Nov 2020 17:38:07
Coding entries removed.	Alma Guel (b) (4)	13 Nov 2020 17:37:27
User entered 'Levothyroxine' reason for change:	Alma Guel (b) (4)	13 Nov 2020 17:37:27
Data Entry Error		
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 SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:27:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:27:33
Data point term sent to Coder	System	25 Aug 2020 15:26:50
User entered 'SYNTHROID'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:29
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:31
User entered 'HYPOTHYROIDISM'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:33
User entered '100'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:35
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 04:26:01
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)	09 Sep 2020 21:03:05
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 21:02:58
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).		09 Sep 2020 17:14:02
User entered 'Other (OTHER)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:38
User entered empty; reason for change Data Entry Error		09 Sep 2020 21:02:58
User entered 'MCG'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:39
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:42
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:44
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:45
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:47
User entered 'UN UNK 2017'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:49
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:50
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:54
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:54:56
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:26:38

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:54:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:54:39
Data point term sent to Coder	System	25 Aug 2020 15:27:55
User entered 'AMITRIPTYLINE'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:30
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:32
User entered 'ANXIETY'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:40
User entered '100'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:41
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:42
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:44
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:46
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:51
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:30:52
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:04
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).		14 Oct 2020 11:35:07
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'Medical History has been updated Data enter in error' (Site from DM).	John Villegas (b) (4) (b) (4)	01 Oct 2020 17:30:08
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:44:47
User entered 'UN UNK 2016'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:05
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:07
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:09
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:31:10
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:27:34

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:35:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
Data point term sent to Coder	System	25 Aug 2020 15:28:56
User entered 'SERTRALINE'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:35:36
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:35:47
User entered 'ANXIETY'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:35:49
User entered '100'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:35:53
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:35:54
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:35:55
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:35:59
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:36:00
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Nov 2020 16:36:02
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:55:29
User entered 'UN UNK 2017'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:55:31
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:55:34
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:55:36
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:55:37
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:28:19

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:30:30
Data point term sent to Coder	System	25 Aug 2020 15:29:59
User entered 'ASA'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:20
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:22
User entered 'CARDIAC PROPHYLAXIS'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:26
User entered '81'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:27
User entered 'mg (mg)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:29
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:33
User entered 'once daily (QD)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:34
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:36
User entered 'Oral (ORAL)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:38
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:39
User entered 'UN UNK 2010'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:41
User entered '0'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:43
User entered 'Yes (Y)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:44
User entered empty.	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:23:45
User entered 'No (N)'	Melody Dufrene (b) (4) (b) (4)	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:29:05

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:23:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:23:32
Data point term sent to Coder User entered 'tylenol'	System (b) (4), (b) (6)	05 Oct 2020 23:22:12 05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:09
User entered 'No (N)'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:15
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).		19 Nov 2020 20:03:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'does not meet AE reporting Criteria.' (Site from DM).	John Villegas (b) (4) (b) (4)	13 Nov 2020 23:02:36

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:49:35
User entered 'injection site pain'	(b) (4), (b) (6)	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:16
User entered '500'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:18
User entered 'mg (mg)'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:21
User entered empty.		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:23
User entered 'as needed (PRN)'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:25
User entered empty.		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:27
User entered 'Oral (ORAL)'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:28
User entered empty.		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:30
User entered '19 Aug 2020'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:32
User entered '0'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:33
User entered 'No (N)'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:35
User entered '20 Aug 2020'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:37
User entered 'Yes (Y)'		05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User entered empty.	System	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User entered empty.	System	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:45
User entered empty.	System	05 Oct 2020 23:21:53

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:24:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:24:25
Data point term sent to Coder User entered 'zofran'	System (b) (4), (b) (6)	05 Oct 2020 23:23:12 05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:47
User entered 'No (N)'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:49
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		23 Nov 2020 09:08:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'AE log updated' (Site from DM).	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:46:40
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:50:24
User entered 'nausea'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:55
User entered '8'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:57
User entered 'mg (mg)'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:58
User entered empty.		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:36:00
User entered 'as needed (PRN)'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:42:34
User entered empty.		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:42:36
User entered 'Oral (ORAL)'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:42:38
User entered empty.		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:42:39
User entered '26 Aug 2020'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:42:41
User entered '0'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:42:43
User entered 'No (N)'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:42:45
User entered '27 Aug 2020'		05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:58:53
User closed query 'Per CDM re-query: The response indicates updated; However the response for the question 'Was this medication taken for solicited event?' is still Yes. As the event occurred outside the solicited period (after 7 days of dosing), please review the response and update as appropriate. ' (Site from DM).		30 Nov 2020 04:43:55
Query 'Per CDM re-query: The response indicates updated; However the response for the question 'Was this medication taken for solicited event?' is still Yes. As the event occurred outside the solicited period (after 7 days of dosing), please review the response and update as appropriate. ' answered with 'data updated' (Site from DM).	Alma Guel (b) (4)	23 Nov 2020 20:56:40
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	23 Nov 2020 20:56:32
User closed query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:19:15
User opened query 'Per CDM re-query: The response indicates updated; However the response for the question 'Was this medication taken for solicited event?' is still Yes. As the event occurred outside the solicited period (after 7 days of dosing), please review the response and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:19:13
Query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however, the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated per query' (Site from DM).	Tisha Davis (b) (4) (b) (4)	19 Nov 2020 22:46:13

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event? = Yes, however the medication was taken not within the solicited period for this subject. Please confirm and update as appropriate, otherwise clarify.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 20:50:39
	(b) (4), (b) (6)	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User entered empty.	System	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User entered empty.	System	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:51
User entered empty.	System	05 Oct 2020 23:22:33

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:25:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 23:25:25
Data point term sent to Coder User entered 'tylenol'	System (b) (4), (b) (6)	05 Oct 2020 23:24:14 05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:52
User entered 'No (N)'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:34:55
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ELEVATED TEMPERATURE, BODY ACHES, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ELEVATED TEMPERATURE, BODY ACHES, FATIGUE did not meet the AE reporting criteria.' (Site from DM).		19 Nov 2020 20:03:58
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ELEVATED TEMPERATURE, BODY ACHES, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ELEVATED TEMPERATURE, BODY ACHES, FATIGUE did not meet the AE reporting criteria.' answered with 'does not meet AE reporting Criteria.' (Site from DM).	John Villegas (b) (4) (b) (4)	13 Nov 2020 23:03:32

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ELEVATED TEMPERATURE, BODY ACHES, FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ELEVATED TEMPERATURE, BODY ACHES, FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:49:07
User entered 'elevated temperature, body aches, fatigue'	(b) (4), (b) (6)	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:00
User entered '1000'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:02
User entered 'mg (mg)'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:08
User entered empty.		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:10
User entered 'four times daily (QID)'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:11
User entered empty.		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:13
User entered 'Oral (ORAL)'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:14
User entered empty.		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:19
User entered '22 Sep 2020'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:21
User entered '0'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:23
User entered 'No (N)'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:24
User entered '24 Sep 2020'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:35:25
User entered 'Yes (Y)'		05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User entered '4'	System	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User entered '1'	System	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:18:56
User entered '804 (804)'	System	05 Oct 2020 23:23:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 19:53:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 19:53:08
Data point term sent to Coder	System	09 Dec 2020 19:51:53
Coding entries removed.	Alma Guel (b) (4)	09 Dec 2020 19:51:37
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:07:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:53:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 03:53:07
Data point term sent to Coder	System	23 Nov 2020 19:25:17
User entered 'Apixaban'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).		23 Mar 2021 12:28:40
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'Wouldn't prophylaxis make since the purpose of a prophylaxis is to prevent disease and this medication is taken to prevent the indication from happening again?' (Site from DM).	John Villegas (b) (4) (b) (4)	19 Mar 2021 18:02:22
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:40:56
User signature succeeded.	William Seger (b) (4) (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 15:56:50
DataPoint Un-verified.	Alma Guel (b) (4)	09 Dec 2020 19:51:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 19:51:37
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:07:56
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.		09 Mar 2021 12:40:52
' canceled (Site from DM).		
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	09 Mar 2021 12:40:48
' (Site from DM).		
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:56:53
DataPoint Un-verified.	Alma Guel (b) (4)	09 Dec 2020 19:51:37
User entered 'Pulmonary Embolism' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 19:51:37
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:07:57
User entered 'Blood Clots'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 21:10:33
User entered '10' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 21:10:33
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:07:59
User entered '5'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:08:03
User entered 'mg (mg)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:08:05
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 21:10:33
User entered 'twice daily (BID)' reason for change:	Alma Guel (b) (4)	22 Jan 2021 21:10:33
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:08:07
User entered 'other (OTHER)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Per DM CLR: Please record tapering doses in separate entries. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 07:04:28
DataPoint Verified.		22 Jan 2021 21:30:52
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 21:10:33
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 21:10:33
Query 'Per DM CLR: Please record tapering doses in separate entries. Update as appropriate. ' answered with 'updated' (Site from DM).	Alma Guel (b) (4)	22 Jan 2021 21:09:59
User opened query 'Per DM CLR: Please record tapering doses in separate entries. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:54:38
DataPoint Verified.		25 Nov 2020 16:08:08
User entered '2 tabs bid for 7 days then 1 tab bid'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:08:10
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:08:12
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:08:15
User entered '4 Nov 2020'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:08:16
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 21:12:47
User entered 'No (N)' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 21:12:47
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:08:17
User entered 'Yes (Y)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 21:12:47
User entered '11 Nov 2020' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 21:12:47
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 16:08:19
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 16:08:20
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User entered '2'	System	22 Jan 2021 21:10:33
User entered empty.	System	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User entered '1'	System	22 Jan 2021 21:10:33
User entered empty.	System	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:03
User entered '804 (804)'	System	22 Jan 2021 21:10:33
User entered empty.	System	23 Nov 2020 19:25:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 12:00:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 12:00:53
Data point term sent to Coder	System	09 Dec 2020 19:47:46
Coding entries removed.	Alma Guel (b) (4)	09 Dec 2020 19:47:26
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:54:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 04:15:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 04:15:03
Data point term sent to Coder	System	23 Nov 2020 19:26:19
User entered 'Tramadol'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:54:05
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:58:05
DataPoint Un-verified.	Alma Guel (b) (4)	09 Dec 2020 19:47:26
User entered 'LEFT CALF PAIN (secondary to deep vein thrombosis)' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 19:47:26
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:54:03
User entered 'Left Calf Pain'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:54:01
User entered '50'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:54:00
User entered 'mg (mg)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:56
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:54
User entered 'as needed (PRN)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:53
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:52
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:47
User entered empty.	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:46
User entered '4 Nov 2020'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:44
User entered '0'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:43
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:42
User entered '12 Nov 2020'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 15:53:40
User entered 'No (N)'	Alma Guel (b) (4)	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User entered empty.	System	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User entered empty.	System	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:08
User entered empty.	System	23 Nov 2020 19:26:08

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 21:15:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 21:15:06
Data point term sent to Coder	System	22 Jan 2021 21:14:09
User entered 'Apixaban'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered 'Yes (Y)'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered 'Pulmonary Embolism'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered '5'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered 'mg (mg)'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered 'twice daily (BID)'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered 'Oral (ORAL)'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered '12 Nov 2020'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered '0'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered 'Yes (Y)'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered empty.	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:30:52
User entered 'No (N)'	Alma Guel (b) (4)	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Jan 2021 21:14:04

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 22:48:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 22:48:18
Data point term sent to Coder	System	31 Mar 2021 22:47:30
User entered 'Enoxaparin Sodium'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Pulmonary Embolism'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '77.273'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'mg (mg)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	31 Mar 2021 22:47:27
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	31 Mar 2021 22:47:27
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	31 Mar 2021 22:47:06
User entered 'once (ONCE)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '0'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	31 Mar 2021 22:47:27
User entered '04 Nov 2020' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:27
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	31 Mar 2021 22:47:06
User entered '04 Mar 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User entered empty.	System	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User entered empty.	System	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:43
User entered empty.	System	31 Mar 2021 22:47:06

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 22:50:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 22:50:07
Data point term sent to Coder	System	31 Mar 2021 22:49:31
User entered 'Acetaminophen'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Pulmonary Embolism'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '1000'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'mg (mg)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
DataPoint Verified.		14 Apr 2021 16:32:32
User closed query 'The frequency is every four hours which is 6 times a day. please change the response as applicable.' (Site from CRA).		14 Apr 2021 16:32:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
Query 'The frequency is every four hours which is 6 times a day. please change the response as applicable.' answered with '6 times daily unavailable' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:09:54
User opened query 'The frequency is every four hours which is 6 times a day. please change the response as applicable.' (Site from CRA).		05 Apr 2021 21:23:20
DataPoint Un-verified.		05 Apr 2021 21:22:08
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'other (OTHER)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Q4H'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Oral (ORAL)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '0'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User entered empty.	System	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User entered empty.	System	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:52
User entered empty.	System	31 Mar 2021 22:48:37

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
DataPoint Verified.		19 Apr 2021 16:15:55
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 06:57:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:57:45
Data point term sent to Coder	System	07 Apr 2021 16:13:01
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 16:12:33
User entered 'KETOROLAC TROMETHAMINE' reason for change: Per Query Resolution		07 Apr 2021 16:12:33
DataPoint Verified.		05 Apr 2021 21:19:36
Data point term sent to Coder	System	31 Mar 2021 22:50:32
User entered 'Ketorolac Tromethamine Aspirin'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Pulmonary Embolism'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
DataPoint Verified.		19 Apr 2021 15:32:23
User closed query 'Thank you for updating the dosage. Please create another logline to record 243 mg of ketorolac tromethamine which was taken orally by the subject. ' (Site from CRA).		19 Apr 2021 15:32:21
Query 'Thank you for updating the dosage. Please create another logline to record 243 mg of ketorolac tromethamine which was taken orally by the subject. answered with 'Aspirin 243 mg added to CM log' (Site from CRA).		15 Apr 2021 16:44:39
User opened query 'Thank you for updating the dosage. Please create another logline to record 243 mg of ketorolac tromethamine which was taken orally by the subject. ' (Site from CRA).		14 Apr 2021 16:41:16
User closed query 'Per medical records, 30mg was administered through IV and 243 mg was administered orally. Therefore, please add this medication under two different loglines in both EDC & Source. ' (Site from CRA).		14 Apr 2021 16:41:16
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
Query 'Per medical records, 30mg was administered through IV and 243 mg was administered orally. Therefore, please add this medication under two different loglines in both EDC & Source. ' answered with 'Changed data per query' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:14:45
User entered '30' reason for change: Data Entry Error		07 Apr 2021 16:12:52
User entered '30mg' reason for change: Data Entry Error		07 Apr 2021 16:12:44
DataPoint Un-verified.		07 Apr 2021 16:12:33
User entered '30' reason for change: Data Entry Error		07 Apr 2021 16:12:33
User opened query 'Per medical records, 30mg was administered through IV and 243 mg was administered orally. Therefore, please add this medication under two different loglines in both EDC & Source. ' (Site from CRA).		05 Apr 2021 21:46:23

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '30/243'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'mg (mg)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:30:07
User closed query 'The frequency is four times a day - please change the response as applicable' (Site from CRA).		12 Apr 2021 00:30:03
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	07 Apr 2021 16:15:34
Query 'The frequency is four times a day - please change the response as applicable' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:27:36
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	07 Apr 2021 15:27:26
User entered 'four times daily (QID)' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Apr 2021 15:27:26
User opened query 'The frequency is four times a day - please change the response as applicable' (Site from CRA).		05 Apr 2021 21:24:15
DataPoint Un-verified.		05 Apr 2021 21:23:37
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'other (OTHER)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:30:05
DataPoint Un-verified.		07 Apr 2021 16:15:34
User entered empty; reason for change Per Query Resolution		07 Apr 2021 16:15:34
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'Q6H'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Oral (ORAL)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '03 Nov 2020' reason for change: Data Entry Error	John Villegas (b) (4)	31 Mar 2021 22:51:27
User entered '04 Nov 2020'	(b) (4) John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '0'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User entered '4'	System	07 Apr 2021 15:27:26
User entered empty.	System	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User entered '1'	System	07 Apr 2021 15:27:26
User entered empty.	System	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:19:59
User entered '804 (804)'	System	07 Apr 2021 15:27:26
User entered empty.	System	31 Mar 2021 22:50:01

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:22:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:22:52
Data point term sent to Coder	System	31 Mar 2021 22:51:32
User entered 'Aspirin'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Pulmonary Embolism'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '325'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'mg (mg)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'once daily (QD)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Oral (ORAL)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '03 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '0'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '03 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 22:50:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 22:50:56
User entered 'No (N)' reason for change: Data Entry Error	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:56
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 22:50:51
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User entered '1'	System	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User entered '1'	System	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:04
User entered '804 (804)'	System	31 Mar 2021 22:50:51

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
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)	01 Apr 2021 09:41:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 09:41:28
Data point term sent to Coder	System	31 Mar 2021 22:53:34
User entered 'Sodium Chloride'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Yes (Y)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Deep Venous Thrombosis (Prophylaxis)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '70'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'mL (mL)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:30:57
User closed query 'The frequency is twice a day - please change the response as applicable.' (Site from CRA).		12 Apr 2021 00:30:54
Query 'The frequency is twice a day - please change the response as applicable.' answered with 'changed data per query' (Site from CRA).		07 Apr 2021 16:16:47
User entered 'twice daily (BID)' reason for change: Data Entry Error		07 Apr 2021 16:16:36
User opened query 'The frequency is twice a day - please change the response as applicable.' (Site from CRA).		05 Apr 2021 21:26:14
DataPoint Un-verified.		05 Apr 2021 21:25:51
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'other (OTHER)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:30:59
DataPoint Un-verified.		07 Apr 2021 16:16:36
User entered empty; reason for change Data Entry Error		07 Apr 2021 16:16:36
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'Q12H'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Intravenous (INTRAVENOUS)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '03 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '0'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User entered '2'	System	07 Apr 2021 16:16:36
User entered empty.	System	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User entered '1'	System	07 Apr 2021 16:16:36
User entered empty.	System	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:10
User entered '804 (804)'	System	07 Apr 2021 16:16:36
User entered empty.	System	31 Mar 2021 22:53:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: ALUMINIUM HYDROXIDE/MAGNESIUM HYDROXIDE/SIMETHICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:59:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:59:47
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:19:36
Data point term sent to Coder	System	31 Mar 2021 22:57:39
User entered 'Al Hydrox/ mg Hydrox/ simethicone'	John Villegas (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Yes (Y)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Gastrointestinal Prophylaxis'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '30'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'mL (mL)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:31:16
User closed query 'The frequency is 4 times a day - please change the response as applicable' (Site from CRA).		12 Apr 2021 00:31:10
Query 'The frequency is 4 times a day - please change the response as applicable' answered with 'changed data per query' (Site from CRA).		07 Apr 2021 16:17:45
DataPoint Un-verified.		07 Apr 2021 16:17:07
User entered 'four times daily (QID)' reason for change: Data Entry Error		07 Apr 2021 16:17:07
User opened query 'The frequency is 4 times a day - please change the response as applicable' (Site from CRA).		05 Apr 2021 21:27:11
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'other (OTHER)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:31:14
DataPoint Un-verified.		07 Apr 2021 16:17:07
User entered empty; reason for change Data Entry Error		07 Apr 2021 16:17:07
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'Q6H'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Oral (ORAL)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '0'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:31:27
User closed query 'Per medical records, the end date is 12/4/20/ Please check with the subject and update the field in both EDC & Source. ' (Site from CRA). Query 'Per medical records, the end date is 12/4/20/ Please check with the subject and update the field in both EDC & Source. ' answered with 'changed data per query' (Site from CRA). DataPoint Un-verified.		12 Apr 2021 00:31:24 07 Apr 2021 16:19:03 07 Apr 2021 16:18:53
User entered '04 Dec 2020' reason for change: Data Entry Error		07 Apr 2021 16:18:53
User opened query 'Per medical records, the end date is 12/4/20/ Please check with the subject and update the field in both EDC & Source. ' (Site from CRA). DataPoint Verified.		05 Apr 2021 21:48:04 05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User entered '4'	System	07 Apr 2021 16:17:07
User entered empty.	System	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User entered '1'	System	07 Apr 2021 16:17:07
User entered empty.	System	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:20
User entered '804 (804)'	System	07 Apr 2021 16:17:07
User entered empty.	System	31 Mar 2021 22:57:11

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: MAGNESIUM COMPOUNDS, PRODUCT: MAGNESIUM HYDROXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 07:46:40
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 07:46:40
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 21:19:36
Data point term sent to Coder	System	31 Mar 2021 22:59:40
User entered 'Magnesium Hydroxide'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Yes (Y)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Gastrointestinal Prophylaxis'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '30'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'mL (mL)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'as needed (PRN)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Oral (ORAL)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '0'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:31:43
User closed query 'Per medical records end date is 12/4. please check with the subject if subject continued taking the meds and update it in both source & EDC as applicable.' (Site from CRA). Query 'Per medical records end date is 12/4. please check with the subject if subject continued taking the meds and update it in both source & EDC as applicable.' answered with 'changed data per query' (Site from CRA). DataPoint Un-verified.		12 Apr 2021 00:31:41
		07 Apr 2021 16:19:54
		07 Apr 2021 16:19:46
User entered '04 Dec 2020' reason for change: Data Entry Error		07 Apr 2021 16:19:46
User opened query 'Per medical records end date is 12/4. please check with the subject if subject continued taking the meds and update it in both source & EDC as applicable.' (Site from CRA). DataPoint Verified.		05 Apr 2021 21:49:15
		05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User entered empty.	System	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User entered empty.	System	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:27
User entered empty.	System	31 Mar 2021 22:58:55

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 23:01:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 23:01:12
Data point term sent to Coder	System	31 Mar 2021 23:00:40
User entered 'Ondansetron HCL'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Yes (Y)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Gastrointestinal Prophylaxis'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '4'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'mg (mg)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
User closed query 'The frequency is 6 times a day - please change the response as applicable' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:32:06
Query 'The frequency is 6 times a day - please change the response as applicable' answered with 'Changed data per query' (Site from CRA).		07 Apr 2021 16:20:39
User opened query 'The frequency is 6 times a day - please change the response as applicable' (Site from CRA).		05 Apr 2021 21:28:13
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'other (OTHER)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 00:32:09
DataPoint Un-verified.		07 Apr 2021 16:20:29
User entered '6 times daily' reason for change: Data Entry Error		07 Apr 2021 16:20:29
DataPoint Verified.		05 Apr 2021 21:19:36
User entered 'Q4H'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'Intravenous (INTRAVENOUS)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered empty.	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '0'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered '04 Nov 2020'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User signature succeeded.	William Seger (b) (4)	13 Apr 2021 15:17:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 21:19:36
User entered 'No (N)'	John Villegas (b) (4) (b) (4)	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User entered empty.	System	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User entered empty.	System	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:31
User entered empty.	System	31 Mar 2021 23:00:15

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:31:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 16:45:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 16:45:50
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	15 Apr 2021 16:44:43 15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:31:54
User entered 'No (N)'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:31:56
User entered 'pulmonary embolism'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:31:58
User entered '243'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:01
User entered 'mg (mg)'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:03
User entered empty.		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:04
User entered 'other (OTHER)'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:06
User entered 'every 6 hours'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:07
User entered 'Oral (ORAL)'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:09
User entered empty.		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:11
User entered '03 Nov 2020'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:12
User entered '0'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:14
User entered 'No (N)'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:16
User entered '04 Nov 2020'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:32:17
User entered 'No (N)'		15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User entered empty.	System	15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User entered empty.	System	15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:43:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:21:09
User entered empty.	System	15 Apr 2021 16:44:09

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:43:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:20:42
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:58:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Alma Guel (b) (4)	04 Dec 2020 18:12:25
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 21:28:44

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:01:05
User entered '03 Nov 2020'	Alma Guel (b) (4)	04 Dec 2020 18:15:15

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:01:07
User entered 'CT SCAN - ANGIO CHEST W&WO CONT'	Alma Guel (b) (4)	04 Dec 2020 18:15:15

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:31:20
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 21:07:45
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 21:07:45
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 16:01:11
User entered 'Adverse Event (AE)'	Alma Guel (b) (4)	04 Dec 2020 18:15:15

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:43:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:01:12
User entered empty.	Alma Guel (b) (4)	04 Dec 2020 18:15:15

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:43:19

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:01:21
User entered '3 Nov 2020'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:22:44

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:43:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:01:23
User entered 'CHEST X-RAY'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:22:44

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:31:20
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 21:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 16:01:39
DataPoint Verified.		22 Jan 2021 16:01:35
User entered 'Other (OTHER)' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 20:17:59
User entered 'Adverse Event (AE)'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:22:44

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:43:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:40
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User closed query 'Source doesn't match. Per source, chest x-ray was done due to SAE. Please update the field as applicable. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:31:23
DataPoint Verified.		22 Jan 2021 21:31:20
Query 'Source doesn't match. Per source, chest x-ray was done due to SAE. Please update the field as applicable. ' answered with 'updated' (Site from CRA).	Alma Guel (b) (4)	22 Jan 2021 21:07:07
User entered empty; reason for change Data Entry Error	Alma Guel (b) (4)	22 Jan 2021 21:06:52
User opened query 'Source doesn't match. Per source, chest x-ray was done due to SAE. Please update the field as applicable. ' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 16:02:36
User entered 'Shortness of Breath' reason for change: Data Entry Error	Alma Guel (b) (4)	09 Dec 2020 20:17:59
User entered empty.	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:22:44

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:43:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:43
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:02:40
User entered '3 Nov 2020'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:23:20

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:43:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:43
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:02:44
User entered 'ECG'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:23:20

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:43
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:31:20
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 21:07:23
User entered 'Diagnostic (DIAGNOSTIC)' reason	Alma Guel (b) (4)	22 Jan 2021 21:07:23
for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 16:02:47
User entered 'Adverse Event (AE)'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:23:20

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:43:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:43
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:02:48
User entered empty.	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:23:20

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:43:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:48
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:02:58
User entered '3 Nov 2020'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:24:04

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:43:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:48
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:03:00
User entered 'ULTRA SOUND'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:24:04

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:43:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:48
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 21:31:20
DataPoint Un-verified.	Alma Guel (b) (4)	22 Jan 2021 21:07:32
User entered 'Diagnostic (DIAGNOSTIC)' reason	Alma Guel (b) (4)	22 Jan 2021 21:07:32
for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 16:03:06
User entered 'Adverse Event (AE)'	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:24:04

US3442031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:43:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:48
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:03:07
User entered empty.	Oluwatosin Akingbala (b) (4)	07 Dec 2020 22:24:04

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:00
User entered 'USA-US017-2020-MRNA-1273-P301000003'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:02
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Death

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:03
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:05
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:07
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:09
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:10
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:12
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:16
User entered 'William'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:18
User entered 'Seeger'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:50:33
Un-reviewed for Safety.	Alma Guel (b) (4)	22 Apr 2021 18:50:15
Signature has been broken.	Alma Guel (b) (4)	22 Apr 2021 18:50:15
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Apr 2021 18:50:15
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:42
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 19:33:59
DataPoint Verified.		25 Nov 2020 15:27:35
Un-reviewed for Safety.	System	16 Nov 2020 17:57:10
DataPoint Un-verified.	System	16 Nov 2020 17:57:10
User entered '4505 Boat Club Road, Suite 400A'	System	16 Nov 2020 17:57:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		13 Nov 2020 15:21:16
User closed query 'Please correct the street address. It has to be 4504 boat club road.		13 Nov 2020 15:21:14
' (Site from CRA).		
Query 'Please correct the street address. It has to be 4504 boat club road.		12 Nov 2020 18:56:26
' answered with 'CORRECTED' (Site from CRA).		
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error		12 Nov 2020 18:56:19
User opened query 'Please correct the street address. It has to be 4504 boat club road.		12 Nov 2020 18:05:48
' (Site from CRA).		
DataPoint Un-verified.		12 Nov 2020 18:05:21
DataPoint Verified.		12 Nov 2020 18:05:19
User entered '4505 Boat Club Road, Suite 400A'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:50
User entered 'Fort Worth'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		13 Nov 2020 15:21:22
User entered empty.		12 Nov 2020 18:56:19

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:52
User entered '76135'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:53
User entered 'US'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
	(b) (4)	
User entered '3'	System	10 Dec 2020 19:34:19
User entered '2'	System	16 Nov 2020 17:57:10
User entered '1'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:00
User entered 'USA-US017-2020-MRNA-1273-P301000003'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:02
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:03
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:05
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:07
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:09
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:10
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:12
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:16
User entered 'William'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:18
User entered 'Seeger'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:50:33
Un-reviewed for Safety.	Alma Guel (b) (4)	22 Apr 2021 18:50:15
Signature has been broken.	Alma Guel (b) (4)	22 Apr 2021 18:50:15
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Apr 2021 18:50:15
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:42
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:33:59
DataPoint Verified.		25 Nov 2020 15:27:35
Un-reviewed for Safety.	System	16 Nov 2020 17:57:10
DataPoint Un-verified.	System	16 Nov 2020 17:57:10
User entered '4505 Boat Club Road, Suite 400A'	System	16 Nov 2020 17:57:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		13 Nov 2020 15:21:16
User closed query 'Please correct the street address. It has to be 4504 boat club road. ' (Site from CRA).		13 Nov 2020 15:21:14
Query 'Please correct the street address. It has to be 4504 boat club road. ' answered with 'CORRECTED' (Site from CRA).		12 Nov 2020 18:56:26
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error		12 Nov 2020 18:56:19
User opened query 'Please correct the street address. It has to be 4504 boat club road. ' (Site from CRA).		12 Nov 2020 18:05:48
DataPoint Un-verified.		12 Nov 2020 18:05:21
DataPoint Verified.		12 Nov 2020 18:05:19
User entered '4505 Boat Club Road, Suite 400A'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:50
User entered 'Fort Worth'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (d) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		13 Nov 2020 15:21:22
User entered empty.		12 Nov 2020 18:56:19

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:52
User entered '76135'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:53
User entered 'US'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
	(b) (4)	
User entered '3'	System	10 Dec 2020 19:34:19
User entered '2'	System	16 Nov 2020 17:57:10
User entered '1'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:43:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '09/Nov/2020 18:02'	(b) (4) System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:43:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
User entered 'I'		09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:00
User entered 'USA-US017-2020-MRNA-1273-P301000003'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:02
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:03
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:05
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:07
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:09
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:10
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:12
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:16
User entered 'William'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:18
User entered 'Seeger'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:50:33
Un-reviewed for Safety.	Alma Guel (b) (4)	22 Apr 2021 18:50:15
Signature has been broken.	Alma Guel (b) (4)	22 Apr 2021 18:50:15
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Apr 2021 18:50:15
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:42
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:33:59
DataPoint Verified.		25 Nov 2020 15:27:35
Un-reviewed for Safety.	System	16 Nov 2020 17:57:10
DataPoint Un-verified.	System	16 Nov 2020 17:57:10
User entered '4505 Boat Club Road, Suite 400A'	System	16 Nov 2020 17:57:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		13 Nov 2020 15:21:16
User closed query 'Please correct the street address. It has to be 4504 boat club road. ' (Site from CRA).		13 Nov 2020 15:21:14
Query 'Please correct the street address. It has to be 4504 boat club road. ' answered with 'CORRECTED' (Site from CRA).		12 Nov 2020 18:56:26
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error		12 Nov 2020 18:56:19
User opened query 'Please correct the street address. It has to be 4504 boat club road. ' (Site from CRA).		12 Nov 2020 18:05:48
DataPoint Un-verified.		12 Nov 2020 18:05:21
DataPoint Verified.		12 Nov 2020 18:05:19
User entered '4505 Boat Club Road, Suite 400A'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:50
User entered 'Fort Worth'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		13 Nov 2020 15:21:22
User entered empty.		12 Nov 2020 18:56:19

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:52
User entered '76135'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:53
User entered 'US'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
	(b) (4)	
User entered '3'	System	10 Dec 2020 19:34:19
User entered '2'	System	16 Nov 2020 17:57:10
User entered '1'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:43:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '16/Nov/2020 12:57'	(b) (4) System	16 Nov 2020 17:57:10

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:43:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:33:59
User entered 'I'		16 Nov 2020 17:57:10

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:00
User entered 'USA-US017-2020-MRNA-1273-P301000003'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Serious

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:02
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:03
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:05
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:07
User entered 'Yes (Y)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:09
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:10
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:12
User entered 'No (N)'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:16
User entered 'William'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:18
User entered 'Seeger'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	23 Apr 2021 17:39:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:50:33
Un-reviewed for Safety.	Alma Guel (b) (4)	22 Apr 2021 18:50:15
Signature has been broken.	Alma Guel (b) (4)	22 Apr 2021 18:50:15
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error	Alma Guel (b) (4)	22 Apr 2021 18:50:15
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 18:38:42
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:33:59
DataPoint Verified.		25 Nov 2020 15:27:35
Un-reviewed for Safety.	System	16 Nov 2020 17:57:10
DataPoint Un-verified.	System	16 Nov 2020 17:57:10
User entered '4505 Boat Club Road, Suite 400A'	System	16 Nov 2020 17:57:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		13 Nov 2020 15:21:16
User closed query 'Please correct the street address. It has to be 4504 boat club road. ' (Site from CRA).		13 Nov 2020 15:21:14
Query 'Please correct the street address. It has to be 4504 boat club road. ' answered with 'CORRECTED' (Site from CRA).		12 Nov 2020 18:56:26
User entered '4504 BOAT CLUB ROAD, SUITE 400A' reason for change: Data Entry Error		12 Nov 2020 18:56:19
User opened query 'Please correct the street address. It has to be 4504 boat club road. ' (Site from CRA).		12 Nov 2020 18:05:48
DataPoint Un-verified.		12 Nov 2020 18:05:21
DataPoint Verified.		12 Nov 2020 18:05:19
User entered '4505 Boat Club Road, Suite 400A'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:50
User entered 'Fort Worth'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		13 Nov 2020 15:21:22
User entered empty.		12 Nov 2020 18:56:19

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:52
User entered '76135'	System	09 Nov 2020 18:01:41

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:56:46
DataPoint Verified.		12 Nov 2020 18:05:53
User entered 'US'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:43:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
	(b) (4)	
User entered '3'	System	10 Dec 2020 19:34:19
User entered '2'	System	16 Nov 2020 17:57:10
User entered '1'	System	09 Nov 2020 18:02:44

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:43:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered '10/Dec/2020 14:34'	(b) (4) System	10 Dec 2020 19:34:19

US3442031

Folder: SAE USA-US017-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:43:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	William Seger (b) (4)	13 Feb 2021 00:14:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:34:19