

US3532231 (Prod: Children's Healthcare of Atlanta)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:05:38

All time stamps listed in this document are displayed in GMT

US3532231

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 03:49:30

Generated On: 10 Jun 2021 08:05:38

Participant ID

US3532231

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

US3532231

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 11:07:11

Generated On: 10 Jun 2021 08:05:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3532231

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	True
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) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Date of Informed Consent (*dd MMM yyyy*) 03 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3532231

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3532231

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 11:07:11

Generated On: 10 Jun 2021 08:05:38

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3532231

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3532231

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1952
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 1952
Start Year (derived)	1952
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	DEPRESSION
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 (7)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	CATARACT SURGERY-BOTH EYES
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	AV NODAL RE-ENTRY TACHYCARDIA
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 (10)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	CARDIAC ABLATION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	SINUS SURGERY (TO CORRECT FREQUENT SINUS INFECTIONS)
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1968
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 1968
Start Year (derived)	1968
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	HEMORRHOIDS
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	TORN ROTATOR CUFF
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	SCIATICA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	LEFT BUNDLE BRANCH BLOCK
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	OBSTRUCTIVE SLEEP APNEA
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 (22)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	PAROXYSMAL SVT
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)	

US3532231

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	TRIGEMINAL NEURALGIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	PREMATURE VENTRICULAR CONTRACTIONS
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)	

US3532231

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	CATARACTS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Condition	FREQUENT SINUS INFECTIONS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

US3532231

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 11:07:11

Generated On: 10 Jun 2021 08:05:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:45 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 10:45
Height (<i>xxx.x</i>)	168 cm
Weight (<i>xxx.x</i>)	87.4 kg
BMI (<i>xxx.x</i>)	30.96655 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)	

US3532231

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 11:07:11

Generated On: 10 Jun 2021 08:05:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 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: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 11:07:11

Generated On: 10 Jun 2021 08:05:38

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) 22 Feb 2021 11:07:11

Generated On: 10 Jun 2021 08:05:38

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) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 189688

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) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

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) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

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)	03 SEP 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 10:45
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

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)	03 SEP 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 12:23
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 11:50 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 11:50

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

US3532231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 SEP 2020
Collection time (00:00-23:59)	11:38 (24 HR)
Collection date and time (derived)	03 SEP 2020 11:38

US3532231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:25	03 SEP 2020 11:25
Nasopharyngeal Swab 2	No		

US3532231

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp 03 SEP 2020 12:23

PC Open Date & Time 03 SEP 2020 12:10

PC Close Date & Time 03 SEP 2020 14:40

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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 96.1 °F

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

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

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

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

PC Time Stamp 03 SEP 2020 22:18

PC Open Date & Time 03 SEP 2020 15:35

PC Close Date & Time 04 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

04 SEP 2020 22:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 20:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °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	True
PC Time Stamp	06 SEP 2020 21:51
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 11:35

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °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	08 SEP 2020 22:36
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °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	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	09 SEP 2020 22:57
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

10 SEP 2020 21:54

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

03 SEP 2020 12:24

PC Open Date & Time

03 SEP 2020 12:10

PC Close Date & Time

03 SEP 2020 14:40

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

03 SEP 2020 22:19

PC Open Date & Time

03 SEP 2020 15:35

PC Close Date & Time

04 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

04 SEP 2020 22:54

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

05 SEP 2020 20:24

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

06 SEP 2020 21:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

08 SEP 2020 11:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

08 SEP 2020 22:36

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

09 SEP 2020 22:57

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 12:25
PC Open Date & Time	03 SEP 2020 12:10
PC Close Date & Time	03 SEP 2020 14:40

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 22:20
PC Open Date & Time	03 SEP 2020 15:35
PC Close Date & Time	04 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:55
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

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)

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

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 ☒

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:53
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 11:36
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

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 ☒

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:37
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:58
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3532231

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 21:55
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3532231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	VISIT2

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:06
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

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)	1 OCT 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 11:40
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3532231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 OCT 2020

What was the treatment time? (00:00-23:59) 11:08 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 11:08

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

US3532231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	10:45 (24 HR)
Collection date and time (derived)	1 OCT 2020 10:45

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:40	1 OCT 2020 10:40
Nasopharyngeal Swab 2	No		

US3532231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 11:41

PC Open Date & Time

01 OCT 2020 11:28

PC Close Date & Time

01 OCT 2020 13:58

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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 97.0 °F

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

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

PC Time Stamp	01 OCT 2020 22:28
PC Open Date & Time	01 OCT 2020 14:53
PC Close Date & Time	02 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 20:20

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	95.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	03 OCT 2020 22:59
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °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	04 OCT 2020 23:02
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.9 °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	05 OCT 2020 21:19
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

101.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 OCT 2020 22:15

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

07 OCT 2020 23:21

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.6 °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	False
To PREVENT pain or fever from occurring	True

PC Time Stamp	08 OCT 2020 22:59
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 11:41

PC Open Date & Time

01 OCT 2020 11:28

PC Close Date & Time

01 OCT 2020 13:58

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

01 OCT 2020 22:29

PC Open Date & Time

01 OCT 2020 14:53

PC Close Date & Time

02 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

02 OCT 2020 20:21

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

03 OCT 2020 22:59

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 23:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 21:20

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

06 OCT 2020 22:16

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

07 OCT 2020 23:22

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 11:42
PC Open Date & Time	01 OCT 2020 11:28
PC Close Date & Time	01 OCT 2020 13:58

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 22:31
PC Open Date & Time	01 OCT 2020 14:53
PC Close Date & Time	02 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 20:22
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 23:01
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 23:04
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 21:22
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

	Yes <input type="checkbox"/>
PC Time stamp	06 OCT 2020 22:19
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 23:24
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp 08 OCT 2020 23:00

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 08 OCT 2020 23:01

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 10

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 8

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 08 OCT 2020 23:01

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time	08 OCT 2020 12:00
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PC Close Date & Time	09 OCT 2020 11:59
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PC Time stamp	08 OCT 2020 23:01
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US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you
are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

PC Time stamp

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of **CHILLS** you
are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

PC Time stamp

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	08 OCT 2020 23:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:07:10

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments SUBJECT HOSPITALIZED. PER
WIFE SOME CONFUSION.
If Contact Not Made, please provide Comments NOTES ARE IN CHART.

US3532231

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:09 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 10:09
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	58 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

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.

US3532231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 OCT 2020
Collection time (00:00-23:59)	10:18 (24 HR)
Collection date and time (derived)	29 OCT 2020 10:18

US3532231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:22:04

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

04 NOV 2020 09:11:08

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

12 NOV 2020 12:01:13

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 07:53:30
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 16:13:05
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 00:02:38
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

21 DEC 2020 12:02:47

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

29 DEC 2020 18:34:35

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

18 JAN 2021 12:03:38

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

23 JAN 2021 08:04:04

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

01 FEB 2021 12:01:23

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 159

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 08:06:52

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

22 FEB 2021 12:05:32

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

01 MAR 2021 14:27:59

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

07 MAR 2021 09:10:30

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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	16 MAR 2021 18:31:38
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

23 MAR 2021 18:21:36

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

31 MAR 2021 08:42:00

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

06 APR 2021 12:37:43

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

12 APR 2021 12:48:47

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

17 APR 2021 16:33:42

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 12:41:24
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 <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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 <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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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°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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 <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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 <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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 <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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
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Patient Cloud Close Date & Time	09 MAR 2022 23:59
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US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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="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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	24 AUG 2022 23:59
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US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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 <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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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"/>

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3532231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:05:38

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		01 MAR 2021 14:28:14

US3532231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:43:39

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:43:39

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

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) _____

US3532231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

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.

US3532231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	10:30 (24 HR)
Collection date and time (derived)	22 MAR 2021 10:30

US3532231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:00:37

Generated On: 10 Jun 2021 08:05:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532231

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:00:37

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532231

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Date of Contact	5 NOV 2020
Time of Contact	09:30
Date and Time of Contact (derived)	5 NOV 2020 09:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	3 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	4 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	5 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	6 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	7 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Date of Visit	5 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	5 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Date of Contact	08 OCT 2020
Time of Contact	18:00
Date and Time of Contact (derived)	08 OCT 2020 18:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Date of Visit	8 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	8 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3532231

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	07 NOV 2020
Day 5	Yes	09 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3532231

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	09:44 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 09:44
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532231

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 NOV 2020

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

US3532231

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

05 NOV 2020

US3532231

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3532231

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

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

US3532231

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

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.

US3532231

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 08:05:38

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

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

US3532231

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

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

Visit date (dd MMM yyyy)	12 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>

Folder OID	UNBLND_DECIDE
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US3532231

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Date of updated informed consent (dd MMM yyyy) 12 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

09:41 (24 HR)

Collection date and time (derived)

12 JAN 2021 09:41

US3532231

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	09:45
Collection Date and Time (derived)	12 JAN 2021 09:45

US3532231

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 09:16:24

Generated On: 10 Jun 2021 08:05:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input 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)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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AEID	USA-US077-2020-MRNA-1273-P30 1000004
Adverse event	COMMUNITY ACQUIRED PNEUMONIA
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)	10 OCT 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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	16 OCT 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 (2)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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SUBJECT TAKEN TO ED WITH
FEVER, CONFUSION, DARK
URINE . ADMITTED FOR
PNEUMONIA.- WAS TESTED
FOR COVID- NEGATIVE
RESULT. CHEST X-RAY
REVEALED DENSE RIGHT
POSTERIOR PERIHILAR
CONSOLIDATION WITH AIR
BRONCHOGRAMS SUGGESTIVE
OF PNEUMONIA.O2 SAT 95% ON
ROOM AIR. STARTED ON
ROCEPHEN AND
AZITHROMAX.CEFTRIAXONE
AND CEFDINIR DISCONTINUED
DUE TO ELEVATED LIVER
ENZYMES.ULTRA SOUND OF
THE ABDOMEN REVEALED
HEPATIC STEATOSIS AND/OR
CHRONIC LIVER DISEASE

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

AEID

Adverse event

TOXIC ENCEPHALOPATHY

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)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☒

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	NOT RELATED TO VACCINE-RELATED TO PNEUMONIA (LISTED IN SAE DATED 10OCT2020) RESOLVED WITH TREATMENT OF CAP-.NOT AN SAE BUT AN AE PER CRITERIA
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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AEID

Adverse event

HEPATIC STEATOSIS

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)

10 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

AEID

Adverse event

RESPIRATORY ILLNESS

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)

9 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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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <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	SUBJECT C/O NASAL CONGESTION AND SORE THROAT.
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)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

AEID

Adverse event

GENERALIZED MUSCLE ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

01 OCT 2020

Start time (00:00-23:59)

22:30 (24 HR)

AE start date and time (derived)

01 OCT 2020 22:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 OCT 2020

End time (00:00-23:59)

00:00 (24 HR)

AE End Date and Time (derived)

8 OCT 2020 00:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	DAY 8 OF EDIARY
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 OCT 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)	8 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	ENTERED IN DAY 8 EDIARY
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 OCT 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)	8 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	EDIARY ENTRY DAY 8
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)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication FLUVOXAMINE

Prophylaxis Yes ☐
No ☒

Indication HEART ARRHYTHMIA
DEPRESSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:18:01

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
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 (2)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

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 (3)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication BYSTOLIC

Prophylaxis Yes ☐
No ☒

Indication HEART ARRHYTHMIA

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 (4)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	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 (5)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 150

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) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

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 (6)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES AND GENERAL PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	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) _____		
Start date completely unknown		True
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 (8)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES AND GENERAL PAINS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
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 (12)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	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)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (13)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication IPRATROPIUM NASAL 21
MCG/INH (0.03%)

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 21

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	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 (14)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication JOINT PAIN/FEVER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	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)		8 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 8 OCT 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 (15)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication JOINT PAIN/FEVER

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 (15)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	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)		8 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		8 OCT 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 (16)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

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 (16)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication CEFDINIR

Prophylaxis Yes ☐
No ☒

Indication COMMUNITY ACQUIRED
PNEUMONIA

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 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 (19)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication GENERAL PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF DVT

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication METOPROLOL XL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication NAUSEA AND VOMITING

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication VALSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	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)	11 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication SHINGRIX DOSE 1

Prophylaxis Yes ☒
No ☐

Indication PREVENT SHINGLES

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

499 of 3327

EAB) (1725)

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

Name of Medication B-12

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

501 of 3327

EAB) (1725)

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 15:18:01

Generated On: 10 Jun 2021 08:05:38

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 03:49:31

Generated On: 10 Jun 2021 08:05:38

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) 16 Apr 2021 08:39:03

Generated On: 10 Jun 2021 08:05:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 OCT 2020	CHEST X-RAY	Adverse Event	
14 OCT 2020	ABDOMINAL ULTRASOUND	Adverse Event	
10 OCT 2020	BACTERIAL STUDY	Adverse Event	
10 OCT 2020	VIRAL STUDIES	Adverse Event	

US3532231

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:05:38

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: 10 Jun 2021 08:05:38

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 ☐

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

SAEID	USA-US077-2020-MRNA-1273-P301000004
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

SAEID	USA-US077-2020-MRNA-1273-P301000004
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/OCT/2020 15:55
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

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

SAEID	USA-US077-2020-MRNA-1273-P301000004
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/OCT/2020 14:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

SAEID	USA-US077-2020-MRNA-1273-P301000004
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/OCT/2020 12:03
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

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

SAEID	USA-US077-2020-MRNA-1273-P301000004
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/NOV/2020 12:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 03 Apr 2021 03:49:32

Generated On: 10 Jun 2021 08:05:38

SAEID	USA-US077-2020-MRNA-1273-P301000004
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	EVAN
Investigator's Last Name	ANDERSON
Site Address: Street	2015 UPPERGATE DRIVE
Site Address: City	ATLANTA
Site Address: State	GA
Site Address: Postal Code	30323
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	
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.	False

Audit

US3532231 (Prod: Children's Healthcare of Atlanta)

US3532231

Form: Participant Creation

Generated On: 10 Jun 2021 08:05:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'US3532231'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 14:09:25

US3532231

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:01:50

US3532231

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:09:26

US3532231

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:01:50

US3532231

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'SCRN'	System	03 Sep 2020 15:01:50

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered (b) (6) 1944'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:09:27

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '76'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'YEARS'	System	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '76'	System	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Male (M)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'I'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '1' reason for change: New Information	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:46:54
User entered '0'	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12
	(b) (4)	

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:05:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:12

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '03 Sep 2020' reason for change: Data Entry Error	Laila Hussaini (b) (4)	11 Nov 2020 12:28:50
User entered '3 Sep 2020'	Cindy Lubbers (b) (4)	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Sep 2020'	System	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2020'	System	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Amendment 3 (3)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:46:10

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:09:26

US3532231

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:05:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'I'	System	03 Sep 2020 15:46:17

US3532231

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:46:17

US3532231

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:05:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:17:12

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:20:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:20:46
Data point term sent to Coder	System	03 Sep 2020 16:19:39
User entered 'Hypertension'	Cindy Lubbers (b) (4)	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2005'	Cindy Lubbers (b) (4)	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2005'	System	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2005'	System	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 16:18:57

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:20:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:20:46
Data point term sent to Coder	System	03 Sep 2020 16:19:39
User entered 'GERD'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2005'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2005'	System	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2005'	System	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 16:19:16

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:21:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:21:47
Data point term sent to Coder	System	03 Sep 2020 16:20:40
User entered 'Anxiety'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1952'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1952'	System	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1952'	System	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 16:19:43

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:04:42
Data point term sent to Coder	System	03 Sep 2020 19:03:58
User entered 'High Cholesterol'	(b) (4), (b) (6)	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2013'	System	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2013'	System	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:03:35

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:05:42
Data point term sent to Coder	System	03 Sep 2020 19:05:01
User entered 'Depression'	(b) (4), (b) (6)	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2010'	System	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2010'	System	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:04:04

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF and ensure that the laterality of the affected eye is also recorded. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 03:56:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:27:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:27:18
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF and ensure that the laterality of the affected eye is also recorded. Please verify and update as appropriate.' answered with 'added' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	13 Oct 2020 16:19:57
Data point term sent to Coder	System	13 Oct 2020 16:19:11
Coding entries removed.	Cindy Lubbers (b) (4) (b) (4)	13 Oct 2020 16:18:20
User entered 'CATARACT SURGERY-both eyes' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	13 Oct 2020 16:18:20
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF and ensure that the laterality of the affected eye is also recorded. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 04:49:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:06:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:06:42
Data point term sent to Coder	System	03 Sep 2020 19:06:02

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
User entered 'Cataract surgery'	(b) (4), (b) (6)	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 05:21:03
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	13 Oct 2020 16:20:04
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	13 Oct 2020 16:18:20
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 04:49:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2018' reason for change:	(b) (4)	
Data Entry Error	Cindy Lubbers (b) (4)	13 Oct 2020 16:18:20
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2018'	System	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2018'	System	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2018'	System	13 Oct 2020 16:18:20
User entered empty.	System	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2018'	System	13 Oct 2020 16:18:20
User entered empty.	System	03 Sep 2020 19:05:10

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:06:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:06:43
Data point term sent to Coder	System	03 Sep 2020 19:06:02
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:05:45

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: AV nodal reentrant tachycardia - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 05:32:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 05:32:30
Data point term sent to Coder	System	03 Sep 2020 19:18:58
User entered 'AV Nodal re-entry tachycardia'	(b) (4), (b) (6)	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2016'	System	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2016'	System	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:18:51

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:21:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:21:28
Data point term sent to Coder	System	03 Sep 2020 19:19:58
User entered 'Cardiac Ablation'	(b) (4), (b) (6)	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User closed query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 07:07:23
Query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 19:40:35
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 19:40:20
User opened query 'Per DM CLR: Ongoing is marked for a surgical / medical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 04:49:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2016' reason for change:	(b) (4)	
Data Entry Error	Cindy Lubbers (b) (4)	14 Oct 2020 19:40:20
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2016'	System	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2016'	System	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2016'	System	14 Oct 2020 19:40:20
User entered empty.	System	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2016'	System	14 Oct 2020 19:40:20
User entered empty.	System	03 Sep 2020 19:19:18

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Hernia repair, LLT: Hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:20:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:20:45
Data point term sent to Coder	System	03 Sep 2020 19:20:00
User entered 'Hernia Repair'	(b) (4), (b) (6)	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User closed query 'Per CDM: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 03:46:37
Query 'Per CDM: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	24 Nov 2020 17:13:16
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	24 Nov 2020 17:13:10
User opened query 'Per CDM: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:17:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1995' reason for change:	(b) (4)	
Data Entry Error	Cindy Lubbers (b) (4)	24 Nov 2020 17:13:10
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1995'	System	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1995'	System	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1995'	System	24 Nov 2020 17:13:10
User entered empty.	System	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1995'	System	24 Nov 2020 17:13:10
User entered empty.	System	03 Sep 2020 19:19:41

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 11:16:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 11:16:45
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:11:08
Data point term sent to Coder	System	29 Oct 2020 15:35:18
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:37
Coding entries removed.	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:32
User entered 'SINUS SURGERY (to correct frequent sinus infections)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:32
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 04:50:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Paranasal therapeutic procedures, PT: Sinus operation, LLT: Sinus operation - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 19:21:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 19:21:45
Data point term sent to Coder	System	03 Sep 2020 19:21:02

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
User entered 'Sinus Surgery'	(b) (4), (b) (6)	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1988'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1988'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1988'	System	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1988'	System	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1988'	System	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1988'	System	03 Sep 2020 19:20:27

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:21:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:21:45
Data point term sent to Coder	System	03 Sep 2020 19:21:05
User entered 'Enlarged Prostate'	(b) (4), (b) (6)	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1990'	System	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1990'	System	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:20:52

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:27:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:27:49
Data point term sent to Coder	System	03 Sep 2020 19:27:20
User entered 'Osteoarthritis'	(b) (4), (b) (6)	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1968'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1968'	System	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1968'	System	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:26:43

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:31:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:31:40
Data point term sent to Coder	System	03 Sep 2020 19:30:28
User entered 'Erectile Dysfunction'	(b) (4), (b) (6)	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2015'	System	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2015'	System	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:29:34

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:31:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:31:40
Data point term sent to Coder	System	03 Sep 2020 19:30:28
User entered 'Hearing Loss'	(b) (4), (b) (6)	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2015'	System	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2015'	System	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:30:02

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:32:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:32:43
Data point term sent to Coder	System	03 Sep 2020 19:31:34
User entered 'Hemorrhoids'	(b) (4), (b) (6)	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1986'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1986'	System	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1986'	System	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:30:45

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Rotator cuff syndrome, LLT: Rotator cuff tear - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:33:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:33:47
Data point term sent to Coder	System	03 Sep 2020 19:32:36
User entered 'Torn Rotator cuff'	(b) (4), (b) (6)	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2014'	System	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2014'	System	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:31:53

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:33:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:33:47
Data point term sent to Coder	System	03 Sep 2020 19:32:39
User entered 'Sciatica'	(b) (4), (b) (6)	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2005'	System	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2005'	System	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:32:31

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Bundle branch block left, LLT: Left bundle branch block - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:34:48
Data point term sent to Coder	System	03 Sep 2020 19:33:42
User entered 'Left Bundle Branch Block'	(b) (4), (b) (6)	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1995'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1995'	System	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1995'	System	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:33:17

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 17:57:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 17:57:01
Data point term sent to Coder	System	24 Nov 2020 17:14:54
Coding entries removed.	Kathy Stephens (b) (4)	24 Nov 2020 17:14:32
User entered 'obstructive sleep apnea' reason for change: Data Entry Error	Kathy Stephens (b) (4)	24 Nov 2020 17:14:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Respiratory tract therapeutic procedures NEC, PT: Continuous positive airway pressure, LLT: Continuous positive airway pressure - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:38:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:38:45
Data point term sent to Coder	System	03 Sep 2020 19:36:48
User entered 'OSAM CPAP'	(b) (4), (b) (6)	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User closed query 'Per CDM: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 03:48:10
Query 'Per CDM: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' answered with 'updated name of MH' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	24 Nov 2020 17:14:45
User opened query 'Per CDM: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:19:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2017'	System	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2017'	System	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:35:58

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Supraventricular tachycardia, LLT: Paroxysmal supraventricular tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:38:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 14:38:47
Data point term sent to Coder	System	03 Sep 2020 19:36:48
User entered 'Paroxysmal SVT'	(b) (4), (b) (6)	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2016'	System	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2016'	System	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:36:23

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Trigeminal disorders, PT: Trigeminal neuralgia, LLT: Trigeminal neuralgia - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 15:24:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 15:24:53
Data point term sent to Coder	System	26 Sep 2020 15:23:32
Coding entries removed.	Cindy Lubbers (b) (4)	26 Sep 2020 15:23:14
User entered 'TRIGEMINAL NEURALGIA' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	26 Sep 2020 15:23:14
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Trigeminal disorders, PT: Trigeminal neuralgia, LLT: Trigeminal neuralgia - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 16:11:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 16:11:51
Data point term sent to Coder	System	03 Sep 2020 19:37:50
User entered 'Trigeminal Nueralgia'	(b) (4), (b) (6)	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2005'	System	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2005'	System	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:36:52

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User closed query 'Per MM: Please, clarify what PVC stands for.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 06:08:34
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:30:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:30:23
Data point term sent to Coder	System	29 Oct 2020 15:36:22
Query 'Per MM: Please, clarify what PVC stands for.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:35:43
Coding entries removed.	Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:35:37
User entered 'Premature ventricular contractions' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:35:37
User opened query 'Per MM: Please, clarify what PVC stands for.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 15:05:38
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:39:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:39:39
Data point term sent to Coder	System	03 Sep 2020 19:37:50
User entered 'PVC'	(b) (4), (b) (6) (b) (4), (b) (6)	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2016'	System	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2016'	System	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	03 Sep 2020 19:37:18

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 16:21:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 16:21:21
Data point term sent to Coder	System	13 Oct 2020 16:20:12
User entered 'Cataracts'	Cindy Lubbers (b) (4)	13 Oct 2020 16:19:27
	(b) (4)	

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2018'	Cindy Lubbers (b) (4)	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 2018'	Cindy Lubbers (b) (4)	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2018'	System	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2018'	System	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 2018'	System	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '2018'	System	13 Oct 2020 16:19:27

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:26:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 04:26:53
Data point term sent to Coder	System	29 Oct 2020 15:34:17
User entered 'frequent sinus infections'	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'I'	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'un UNK 1988'	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered empty.	System	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'Jan 1988'	System	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '1988'	System	29 Oct 2020 15:34:03

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	11 Nov 2020 12:28:57
User entered '3 Sep 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08
	(b) (4)	

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '10:45'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '03 Sep 2020 10:45'	System	11 Nov 2020 12:28:57
User entered '3 Sep 2020 10:45'	System	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '168' cm	(b) (4) Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08
DataPoint set to visible.	(b) (4) System	03 Sep 2020 15:46:17

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '87.4' kg	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08
DataPoint set to visible.	System	03 Sep 2020 15:46:17

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered '30.96655'	System	03 Sep 2020 15:57:08
DataPoint set to visible.	System	03 Sep 2020 15:46:17

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'kg/m2'	System	03 Sep 2020 15:57:08
DataPoint set to visible.	System	03 Sep 2020 15:46:17

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'bpm'	System	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'breaths/min'	System	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'mmHg'	System	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User entered 'mmHg'	System	03 Sep 2020 15:57:08

US3532231

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52

US3532231

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:19

US3532231

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '03 Sep 2020' reason for change: Data Entry Error	Laila Hussaini (b) (4)	11 Nov 2020 12:29:04
User entered '3 Sep 2020'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:19

US3532231

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

US3532231

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

US3532231

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

US3532231

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Sep 2020 13:15:45
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	13 Sep 2020 13:15:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 15:57:52
	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

US3532231

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'I'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

US3532231

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '0'	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

US3532231

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:05:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:44:52
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:57:52

US3532231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:37

US3532231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	11 Nov 2020 12:29:11
User entered '3 Sep 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:37
	(b) (4)	

US3532231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:02:37

US3532231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'VISIT1'	System	03 Sep 2020 15:02:37

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:58

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '189688'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:58

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 15:29:58

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

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)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:58:11

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

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)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:58:11

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:58:11

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:58:11

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:58:11

US3532231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:05:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Etza Peters (b) (4)	25 Sep 2020 16:17:49
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:08:40
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:08:38

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:05:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:05:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:05:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:05:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	11 Nov 2020 12:29:22
User entered '3 Sep 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	03 Sep 2020 16:27:08
User entered '10:45' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 16:27:08
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	03 Sep 2020 16:00:44
User entered '19:45'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered '03 Sep 2020 10:45'	System	11 Nov 2020 12:29:22
User entered '3 Sep 2020 10:45'	System	03 Sep 2020 16:27:08
User entered '3 Sep 2020 19:45'	System	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '97.0' F	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '57'	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'bpm'	System	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '18'	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'breaths/min'	System	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '95'	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'mmHg'	System	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 07:21:37
Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' answered with 'NCS' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:27:13
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 07:41:42
User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:04:44
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'PI aware' (Site from System).	Cindy Lubbers (b) (4) (b) (4)	14 Oct 2020 19:39:10
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:26:51
User entered '57'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'mmHg'	System	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:05:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:05:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered missing code ND - Not Done.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 16:27:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 15:59:18
	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '03 Sep 2020' reason for change: Data Entry Error	Laila Hussaini (b) (4)	11 Nov 2020 12:29:22
User entered '3 Sep 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '12:23' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User entered empty.	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered '03 Sep 2020 12:23'	System	11 Nov 2020 12:29:22
User entered '3 Sep 2020 12:23'	System	03 Sep 2020 16:27:08
User entered empty.	System	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '98.1' F reason for change: Data Entry Error	Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '56' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User entered empty.	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'bpm'	System	03 Sep 2020 16:27:08
User entered empty.	System	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User entered empty.	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'breaths/min'	System	03 Sep 2020 16:27:08
User entered empty.	System	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '108' reason for change: Data Entry Error	(b) (4) Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User entered empty.	(b) (4) Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'mmHg'	System	03 Sep 2020 16:27:08
User entered empty.	System	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '60' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	03 Sep 2020 16:27:08
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'mmHg'	System	03 Sep 2020 16:27:08
User entered empty.	System	03 Sep 2020 15:59:18

US3532231

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:34

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	11 Nov 2020 12:29:30
User entered '3 Sep 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 15:59:34
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:00:44

US3532231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 16:00:44

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

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)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 16:00:44

US3532231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 16:00:44

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '03 Sep 2020' reason for change: Data Entry Error	Laila Hussaini (b) (4)	11 Nov 2020 12:29:38
User entered '3 Sep 2020'	Cindy Lubbers (b) (4)	03 Sep 2020 16:00:44

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '11:50'	Cindy Lubbers (b) (4)	03 Sep 2020 16:00:44

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered '03 Sep 2020 11:50'	System	11 Nov 2020 12:29:38
User entered '3 Sep 2020 11:50'	System	03 Sep 2020 16:00:44

US3532231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Left Arm (LEFT ARM)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:00:44

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'ONCE'	System	03 Sep 2020 16:00:44

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 16:00:44

US3532231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:01:05

US3532231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	11 Nov 2020 12:29:47
User entered '3 Sep 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 16:01:05
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '11:38'	Cindy Lubbers (b) (4)	03 Sep 2020 16:01:05

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered '03 Sep 2020 11:38'	System	11 Nov 2020 12:29:47
User entered '3 Sep 2020 11:38'	System	03 Sep 2020 16:01:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:05:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	11 Nov 2020 12:29:54
User entered '3 Sep 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	03 Sep 2020 16:03:00
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:05:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 16:03:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:03:00

US3532231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:05:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '11:25'	Cindy Lubbers (b) (4)	03 Sep 2020 16:03:00

US3532231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered '03 Sep 2020 11:25'	System	11 Nov 2020 12:29:54
User entered '3 Sep 2020 11:25'	System	03 Sep 2020 16:03:00

US3532231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:05:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Lubbers (b) (4) (b) (4)	03 Sep 2020 16:03:00

US3532231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:03:00

US3532231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:05:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 16:03:00

US3532231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered empty.	System	03 Sep 2020 16:03:00

US3532231

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 16:03:06

US3532231

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'I'	System	03 Sep 2020 16:03:06

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:23:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '910e908e-05ca-4a0e-bd8f-5a67d9dc4ef0' User entered 'Yes (Y)'	System	03 Sep 2020 16:23:26
	System	03 Sep 2020 16:23:26

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:23:11', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '910e908e-05ca-4a0e-bd8f-5a67d9dc4ef0' User entered '98.1'	System	03 Sep 2020 16:23:26
	System	03 Sep 2020 16:23:26

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:23:16', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '910e908e-05ca-4a0e-bd8f-5a67d9dc4ef0'	System	03 Sep 2020 16:23:26
User entered 'No (N)'	System	03 Sep 2020 16:23:26

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:23:25', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '910e908e-05ca-4a0e-bd8f-5a67d9dc4ef0' User entered '03 Sep 2020 12:23'	System	03 Sep 2020 16:23:26
	System	03 Sep 2020 16:23:26

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 12:10'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 14:40'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:16:50', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'cf35893e-9472-464f-b968-967c1c46e27d' User entered 'Yes (Y)'	System	04 Sep 2020 02:18:07
	System	04 Sep 2020 02:18:07

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:17:07', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'cf35893e-9472-464f-b968-967c1c46e27d' User entered '96.1'	System	04 Sep 2020 02:18:07
	System	04 Sep 2020 02:18:07

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:17:17', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'cf35893e-9472-464f-b968-967c1c46e27d' User entered 'Yes (Y)'	System	04 Sep 2020 02:18:07
	System	04 Sep 2020 02:18:07

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject states meds were taken for arthritis related pain' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 05:59:07
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).	Cindy Lubbers (b) (4)	11 Sep 2020 20:29:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:17:31', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'cf35893e-9472-464f-b968-967c1c46e27d'	System	04 Sep 2020 02:18:07
User entered '1'	System	04 Sep 2020 02:18:07

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:17:31', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'cf35893e-9472-464f-b968-967c1c46e27d' User entered '0'	System	04 Sep 2020 02:18:07
	System	04 Sep 2020 02:18:07

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:18:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'cf35893e-9472-464f-b968-967c1c46e27d' User entered '03 Sep 2020 22:18'	System	04 Sep 2020 02:18:07
	System	04 Sep 2020 02:18:07

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 15:35'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 2'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:52:51', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7bd105b7-b1fa-4fd5-873f-dd5242e2a528'	System	05 Sep 2020 02:53:53
User entered 'Yes (Y)'	System	05 Sep 2020 02:53:53

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:53:03', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7bd105b7-b1fa-4fd5-873f-dd5242e2a528' User entered '97.7'	System	05 Sep 2020 02:53:53
	System	05 Sep 2020 02:53:53

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:53:23', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7bd105b7-b1fa-4fd5-873f-dd5242e2a528'	System	05 Sep 2020 02:53:53
User entered 'No (N)'	System	05 Sep 2020 02:53:53

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:53:51', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7bd105b7-b1fa-4fd5-873f-dd5242e2a528' User entered '04 Sep 2020 22:53'	System	05 Sep 2020 02:53:53
	System	05 Sep 2020 02:53:53

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 3'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:23:09', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6091489e-3c7e-42e9-8d14-6ee473db389c' User entered 'Yes (Y)'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:23:17', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6091489e-3c7e-42e9-8d14-6ee473db389c' User entered '98.0'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:23:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6091489e-3c7e-42e9-8d14-6ee473db389c' User entered 'No (N)'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:23:33', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6091489e-3c7e-42e9-8d14-6ee473db389c' User entered '05 Sep 2020 20:23'	System	06 Sep 2020 00:23:37
	System	06 Sep 2020 00:23:37

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 4'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:51:17', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'af9d545b-6fea-438c-ab06-10bec1a46537'	System	07 Sep 2020 01:52:00
User entered 'Yes (Y)'	System	07 Sep 2020 01:52:00

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:51:25', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'af9d545b-6fea-438c-ab06-10bec1a46537'	System	07 Sep 2020 01:52:00
User entered '97.6'	System	07 Sep 2020 01:52:00

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:51:35', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'af9d545b-6fea-438c-ab06-10bec1a46537'	System	07 Sep 2020 01:52:00
User entered 'Yes (Y)'	System	07 Sep 2020 01:52:00

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject states meds were taken for arthritis related pain' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 05:59:20
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).	Cindy Lubbers (b) (4)	11 Sep 2020 20:30:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:51:49', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'af9d545b-6fea-438c-ab06-10bec1a46537'	(b) (4)	
User entered '1'	System	07 Sep 2020 01:52:00
	System	07 Sep 2020 01:52:00
	System	07 Sep 2020 01:52:00

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User closed query 'Per the participant response, medication was taken to prevent 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 prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject states meds were taken for arthritis related pain' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 05:59:23
User opened query 'Per the participant response, medication was taken to prevent 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).	Cindy Lubbers (b) (4)	11 Sep 2020 20:30:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:51:49', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'af9d545b-6fea-438c-ab06-10bec1a46537'	(b) (4)	
User entered '1'	System	07 Sep 2020 01:52:00
	System	07 Sep 2020 01:52:00
	System	07 Sep 2020 01:52:00

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:51:58', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'af9d545b-6fea-438c-ab06-10bec1a46537'	System	07 Sep 2020 01:52:00
User entered '06 Sep 2020 21:51'	System	07 Sep 2020 01:52:00

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 5'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:35:16', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a56592bb-f8c5-4bc4-a136-fe279a497591' User entered 'Yes (Y)'	System	08 Sep 2020 15:35:50
	System	08 Sep 2020 15:35:50

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:35:35', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a56592bb-f8c5-4bc4-a136-fe279a497591' User entered '97.6'	System	08 Sep 2020 15:35:50
	System	08 Sep 2020 15:35:50

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:35:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a56592bb-f8c5-4bc4-a136-fe279a497591' User entered 'No (N)'	System	08 Sep 2020 15:35:50
	System	08 Sep 2020 15:35:50

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:35:47', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a56592bb-f8c5-4bc4-a136-fe279a497591' User entered '08 Sep 2020 11:35'	System	08 Sep 2020 15:35:50
	System	08 Sep 2020 15:35:50

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 6'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:35:17', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4d4e8974-88ad-4bb7-9b51-29328379b0bb' User entered 'Yes (Y)'	System	09 Sep 2020 02:36:04
	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:35:28', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4d4e8974-88ad-4bb7-9b51-29328379b0bb' User entered '98.2'	System	09 Sep 2020 02:36:04
	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:35:33', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4d4e8974-88ad-4bb7-9b51-29328379b0bb'	System	09 Sep 2020 02:36:04
User entered 'Yes (Y)'	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject states meds were taken for arthritis related pain' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 05:59:32
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).	Cindy Lubbers (b) (4)	11 Sep 2020 20:30:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:35:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4d4e8974-88ad-4bb7-9b51-29328379b0bb'	System	09 Sep 2020 02:36:04
User entered '1'	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:35:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4d4e8974-88ad-4bb7-9b51-29328379b0bb' User entered '0'	System	09 Sep 2020 02:36:04
	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:36:01', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4d4e8974-88ad-4bb7-9b51-29328379b0bb' User entered '08 Sep 2020 22:36'	System	09 Sep 2020 02:36:04
	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 7'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:56:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4e510795-a933-4015-909c-f984f6f823f9'	System	10 Sep 2020 02:57:14
User entered 'Yes (Y)'	System	10 Sep 2020 02:57:14

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:56:47', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4e510795-a933-4015-909c-f984f6f823f9' User entered '97.4'	System	10 Sep 2020 02:57:14
	System	10 Sep 2020 02:57:14

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:56:55', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4e510795-a933-4015-909c-f984f6f823f9'	System	10 Sep 2020 02:57:14
User entered 'Yes (Y)'	System	10 Sep 2020 02:57:14

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4e510795-a933-4015-909c-f984f6f823f9' User entered '0'	System	10 Sep 2020 02:57:14
	System	10 Sep 2020 02:57:14

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User closed query 'Per the participant response, medication was taken to prevent 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 prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject states meds were taken for arthritis related pain' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 05:59:37
User opened query 'Per the participant response, medication was taken to prevent 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).	Cindy Lubbers (b) (4)	11 Sep 2020 20:31:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4e510795-a933-4015-909c-f984f6f823f9'	(b) (4)	
User entered '1'	System	10 Sep 2020 02:57:14
	System	10 Sep 2020 02:57:14
	System	10 Sep 2020 02:57:14

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:09', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '4e510795-a933-4015-909c-f984f6f823f9' User entered '09 Sep 2020 22:57'	System	10 Sep 2020 02:57:14
	System	10 Sep 2020 02:57:14

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	09 Sep 2020 02:36:04
User entered 'Day 8'	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-10T21:53:59', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '3ad0e182-cf69-4eb6-97b7-e87643d6a73b' User entered 'Yes (Y)'	System	11 Sep 2020 01:54:37
	System	11 Sep 2020 01:54:37

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-10T21:54:22', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '3ad0e182-cf69-4eb6-97b7-e87643d6a73b' User entered '97.8'	System	11 Sep 2020 01:54:37
	System	11 Sep 2020 01:54:37

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-10T21:54:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '3ad0e182-cf69-4eb6-97b7-e87643d6a73b' User entered 'No (N)'	System	11 Sep 2020 01:54:37
	System	11 Sep 2020 01:54:37

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-10T21:54:36', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '3ad0e182-cf69-4eb6-97b7-e87643d6a73b' User entered '10 Sep 2020 21:54'	System	11 Sep 2020 01:54:37
	System	11 Sep 2020 01:54:37

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:24:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '97fcd191-d946-442e-b3d2-b7f5068639bb' User entered 'None (1)'	System	03 Sep 2020 16:24:45
	System	03 Sep 2020 16:24:45

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:24:08', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '97fcd191-d946-442e-b3d2-b7f5068639bb' User entered 'No (N)'	System	03 Sep 2020 16:24:45
	System	03 Sep 2020 16:24:45

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:24:14', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '97fcd191-d946-442e-b3d2-b7f5068639bb' User entered 'No (N)'	System	03 Sep 2020 16:24:45
	System	03 Sep 2020 16:24:45

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:24:31', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '97fcd191-d946-442e-b3d2-b7f5068639bb' User entered 'None (1)'	System	03 Sep 2020 16:24:45
	System	03 Sep 2020 16:24:45

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:24:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '97fcd191-d946-442e-b3d2-b7f5068639bb' User entered '03 Sep 2020 12:24'	System	03 Sep 2020 16:24:45
	System	03 Sep 2020 16:24:45

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 12:10'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 14:40'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:18:12', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '470603fe-3909-424c-b98e-783bc17c50ec' User entered 'None (1)'	System	04 Sep 2020 02:19:10
	System	04 Sep 2020 02:19:10

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:18:16', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '470603fe-3909-424c-b98e-783bc17c50ec' User entered 'No (N)'	System	04 Sep 2020 02:19:10
	System	04 Sep 2020 02:19:10

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:18:30', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '470603fe-3909-424c-b98e-783bc17c50ec' User entered 'No (N)'	System	04 Sep 2020 02:19:10
	System	04 Sep 2020 02:19:10

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:18:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '470603fe-3909-424c-b98e-783bc17c50ec'	System	04 Sep 2020 02:19:10
User entered 'None (1)'	System	04 Sep 2020 02:19:10

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:19:05', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '470603fe-3909-424c-b98e-783bc17c50ec'	System	04 Sep 2020 02:19:10
User entered '03 Sep 2020 22:19'	System	04 Sep 2020 02:19:10

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 15:35'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 2'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:53:59', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd5cdd6be-fa69-456e-ab84-5a0fa37a89ec'	System	05 Sep 2020 02:54:29
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 02:54:29

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:03', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd5cdd6be-fa69-456e-ab84-5a0fa37a89ec'	System	05 Sep 2020 02:54:29
User entered 'No (N)'	System	05 Sep 2020 02:54:29

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:07', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd5cdd6be-fa69-456e-ab84-5a0fa37a89ec' User entered 'No (N)'	System	05 Sep 2020 02:54:29
	System	05 Sep 2020 02:54:29

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:11', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd5cdd6be-fa69-456e-ab84-5a0fa37a89ec' User entered 'None (1)'	System	05 Sep 2020 02:54:29
	System	05 Sep 2020 02:54:29

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd5cdd6be-fa69-456e-ab84-5a0fa37a89ec' User entered '04 Sep 2020 22:54'	System	05 Sep 2020 02:54:29
	System	05 Sep 2020 02:54:29

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 3'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:23:45', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '04667af7-f96e-4beb-b254-8f798b325e68'	System	06 Sep 2020 00:24:44
User entered 'None (1)'	System	06 Sep 2020 00:24:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:23:48', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '04667af7-f96e-4beb-b254-8f798b325e68' User entered 'No (N)'	System	06 Sep 2020 00:24:44
	System	06 Sep 2020 00:24:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:23:56', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '04667af7-f96e-4beb-b254-8f798b325e68'	System	06 Sep 2020 00:24:44
User entered 'No (N)'	System	06 Sep 2020 00:24:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '04667af7-f96e-4beb-b254-8f798b325e68' User entered 'None (1)'	System	06 Sep 2020 00:24:44
	System	06 Sep 2020 00:24:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:09', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '04667af7-f96e-4beb-b254-8f798b325e68' User entered '05 Sep 2020 20:24'	System	06 Sep 2020 00:24:44
	System	06 Sep 2020 00:24:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 4'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:08', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8efed18d-c9de-4c27-a1bf-9b77d1c1c1eb'	System	07 Sep 2020 01:52:28
User entered 'None (1)'	System	07 Sep 2020 01:52:28

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:07', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8efed18d-c9de-4c27-a1bf-9b77d1c1c1eb'	System	07 Sep 2020 01:52:28
User entered 'No (N)'	System	07 Sep 2020 01:52:28

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:11', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8efed18d-c9de-4c27-a1bf-9b77d1c1c1eb' User entered 'No (N)'	System	07 Sep 2020 01:52:28
	System	07 Sep 2020 01:52:28

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8efed18d-c9de-4c27-a1bf-9b77d1c1c1eb'	System	07 Sep 2020 01:52:28
User entered 'None (1)'	System	07 Sep 2020 01:52:28

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8efed18d-c9de-4c27-a1bf-9b77d1c1c1eb' User entered '06 Sep 2020 21:52'	System	07 Sep 2020 01:52:28
	System	07 Sep 2020 01:52:28

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 5'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:35:53', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'bc8cbb67-d62e-4306-8e66-189eb7f9c882'	System	08 Sep 2020 15:36:12
User entered 'None (1)'	System	08 Sep 2020 15:36:12

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:35:57', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'bc8cbb67-d62e-4306-8e66-189eb7f9c882'	System	08 Sep 2020 15:36:12
User entered 'No (N)'	System	08 Sep 2020 15:36:12

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'bc8cbb67-d62e-4306-8e66-189eb7f9c882'	System	08 Sep 2020 15:36:12
User entered 'No (N)'	System	08 Sep 2020 15:36:12

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'bc8cbb67-d62e-4306-8e66-189eb7f9c882'	System	08 Sep 2020 15:36:12
User entered 'None (1)'	System	08 Sep 2020 15:36:12

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:08', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'bc8cbb67-d62e-4306-8e66-189eb7f9c882'	System	08 Sep 2020 15:36:12
User entered '08 Sep 2020 11:36'	System	08 Sep 2020 15:36:12

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 6'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:36:08', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'def0d719-367f-4446-9cb3-709e8a88bf85'	System	09 Sep 2020 02:36:31
User entered 'None (1)'	System	09 Sep 2020 02:36:31

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:36:12', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'def0d719-367f-4446-9cb3-709e8a88bf85'	System	09 Sep 2020 02:36:31
User entered 'No (N)'	System	09 Sep 2020 02:36:31

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:36:16', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'def0d719-367f-4446-9cb3-709e8a88bf85'	System	09 Sep 2020 02:36:31
User entered 'No (N)'	System	09 Sep 2020 02:36:31

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:36:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'def0d719-367f-4446-9cb3-709e8a88bf85'	System	09 Sep 2020 02:36:31
User entered 'None (1)'	System	09 Sep 2020 02:36:31

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:36:28', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'def0d719-367f-4446-9cb3-709e8a88bf85'	System	09 Sep 2020 02:36:31
User entered '08 Sep 2020 22:36'	System	09 Sep 2020 02:36:31

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 7'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:15', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '91607702-26b9-4eef-a437-2642b21a0f6a' User entered 'None (1)'	System	10 Sep 2020 02:57:47
	System	10 Sep 2020 02:57:47

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:18', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '91607702-26b9-4eef-a437-2642b21a0f6a' User entered 'No (N)'	System	10 Sep 2020 02:57:47
	System	10 Sep 2020 02:57:47

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:21', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '91607702-26b9-4eef-a437-2642b21a0f6a' User entered 'No (N)'	System	10 Sep 2020 02:57:47
	System	10 Sep 2020 02:57:47

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '91607702-26b9-4eef-a437-2642b21a0f6a' User entered 'None (1)'	System	10 Sep 2020 02:57:47
	System	10 Sep 2020 02:57:47

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:45', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '91607702-26b9-4eef-a437-2642b21a0f6a' User entered '09 Sep 2020 22:57'	System	10 Sep 2020 02:57:47
	System	10 Sep 2020 02:57:47

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:24:58', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a34b1ce4-45a3-4121-a8c4-1cf670ec2a0f' User entered 'None (0)'	System	03 Sep 2020 16:25:35
	System	03 Sep 2020 16:25:35

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:25:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a34b1ce4-45a3-4121-a8c4-1cf670ec2a0f' User entered 'None (0)'	System	03 Sep 2020 16:25:35
	System	03 Sep 2020 16:25:35

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:25:07', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a34b1ce4-45a3-4121-a8c4-1cf670ec2a0f' User entered 'None (0)'	System	03 Sep 2020 16:25:35
	System	03 Sep 2020 16:25:35

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:25:10', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a34b1ce4-45a3-4121-a8c4-1cf670ec2a0f' User entered 'None (0)'	System	03 Sep 2020 16:25:35
	System	03 Sep 2020 16:25:35

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:25:13', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a34b1ce4-45a3-4121-a8c4-1cf670ec2a0f' User entered 'None (0)'	System	03 Sep 2020 16:25:35
	System	03 Sep 2020 16:25:35

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:25:17', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a34b1ce4-45a3-4121-a8c4-1cf670ec2a0f' User entered 'None (0)'	System	03 Sep 2020 16:25:35
	System	03 Sep 2020 16:25:35

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:25:21', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a34b1ce4-45a3-4121-a8c4-1cf670ec2a0f' User entered 'No (N)'	System	03 Sep 2020 16:25:35
	System	03 Sep 2020 16:25:35

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T12:25:33', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a34b1ce4-45a3-4121-a8c4-1cf670ec2a0f' User entered '03 Sep 2020 12:25'	System	03 Sep 2020 16:25:35
	System	03 Sep 2020 16:25:35

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 12:10'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 14:40'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:19:21', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '42f675f1-b0ae-4942-a3a1-47bd44e8e9fd'	System	04 Sep 2020 02:20:45
User entered 'No interference with activity (1)'	System	04 Sep 2020 02:20:45

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:20:25', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '42f675f1-b0ae-4942-a3a1-47bd44e8e9fd' User entered 'None (0)'	System	04 Sep 2020 02:20:45
	System	04 Sep 2020 02:20:45

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:19:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '42f675f1-b0ae-4942-a3a1-47bd44e8e9fd' User entered 'None (0)'	System	04 Sep 2020 02:20:45
	System	04 Sep 2020 02:20:45

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:19:40', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '42f675f1-b0ae-4942-a3a1-47bd44e8e9fd' User entered 'None (0)'	System	04 Sep 2020 02:20:45
	System	04 Sep 2020 02:20:45

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:19:44', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '42f675f1-b0ae-4942-a3a1-47bd44e8e9fd' User entered 'None (0)'	System	04 Sep 2020 02:20:45
	System	04 Sep 2020 02:20:45

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:19:49', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '42f675f1-b0ae-4942-a3a1-47bd44e8e9fd' User entered 'None (0)'	System	04 Sep 2020 02:20:45
	System	04 Sep 2020 02:20:45

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:19:54', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '42f675f1-b0ae-4942-a3a1-47bd44e8e9fd' User entered 'No (N)'	System	04 Sep 2020 02:20:45
	System	04 Sep 2020 02:20:45

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-03T22:20:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '42f675f1-b0ae-4942-a3a1-47bd44e8e9fd' User entered '03 Sep 2020 22:20'	System	04 Sep 2020 02:20:45
	System	04 Sep 2020 02:20:45

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Sep 2020 15:35'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 2'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:32', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ba1f4fc6-90bd-4efe-88e0-2940339b74cf' User entered 'None (0)'	System	05 Sep 2020 02:55:10
	System	05 Sep 2020 02:55:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:36', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ba1f4fc6-90bd-4efe-88e0-2940339b74cf' User entered 'None (0)'	System	05 Sep 2020 02:55:10
	System	05 Sep 2020 02:55:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ba1f4fc6-90bd-4efe-88e0-2940339b74cf' User entered 'None (0)'	System	05 Sep 2020 02:55:10
	System	05 Sep 2020 02:55:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ba1f4fc6-90bd-4efe-88e0-2940339b74cf' User entered 'None (0)'	System	05 Sep 2020 02:55:10
	System	05 Sep 2020 02:55:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:49', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ba1f4fc6-90bd-4efe-88e0-2940339b74cf' User entered 'None (0)'	System	05 Sep 2020 02:55:10
	System	05 Sep 2020 02:55:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:51', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ba1f4fc6-90bd-4efe-88e0-2940339b74cf' User entered 'None (0)'	System	05 Sep 2020 02:55:10
	System	05 Sep 2020 02:55:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:54:55', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ba1f4fc6-90bd-4efe-88e0-2940339b74cf' User entered 'No (N)'	System	05 Sep 2020 02:55:10
	System	05 Sep 2020 02:55:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-04T22:55:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ba1f4fc6-90bd-4efe-88e0-2940339b74cf' User entered '04 Sep 2020 22:55'	System	05 Sep 2020 02:55:10
	System	05 Sep 2020 02:55:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 3'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:15', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c11b6b08-a105-40a9-9be6-f8b73b83a238' User entered 'None (0)'	System	06 Sep 2020 00:25:10
	System	06 Sep 2020 00:25:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c11b6b08-a105-40a9-9be6-f8b73b83a238' User entered 'None (0)'	System	06 Sep 2020 00:25:10
	System	06 Sep 2020 00:25:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:23', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c11b6b08-a105-40a9-9be6-f8b73b83a238' User entered 'None (0)'	System	06 Sep 2020 00:25:10
	System	06 Sep 2020 00:25:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c11b6b08-a105-40a9-9be6-f8b73b83a238' User entered 'None (0)'	System	06 Sep 2020 00:25:10
	System	06 Sep 2020 00:25:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:30', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c11b6b08-a105-40a9-9be6-f8b73b83a238' User entered 'None (0)'	System	06 Sep 2020 00:25:10
	System	06 Sep 2020 00:25:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c11b6b08-a105-40a9-9be6-f8b73b83a238' User entered 'None (0)'	System	06 Sep 2020 00:25:10
	System	06 Sep 2020 00:25:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:42', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c11b6b08-a105-40a9-9be6-f8b73b83a238' User entered 'No (N)'	System	06 Sep 2020 00:25:10
	System	06 Sep 2020 00:25:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-05T20:24:54', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c11b6b08-a105-40a9-9be6-f8b73b83a238' User entered '05 Sep 2020 20:24'	System	06 Sep 2020 00:25:10
	System	06 Sep 2020 00:25:10

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 4'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '722efe2b-a930-48ba-8ab8-0788ec7d2c96'	System	07 Sep 2020 01:53:16
User entered 'None (0)'	System	07 Sep 2020 01:53:16

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:43', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '722efe2b-a930-48ba-8ab8-0788ec7d2c96' User entered 'None (0)'	System	07 Sep 2020 01:53:16
	System	07 Sep 2020 01:53:16

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '722efe2b-a930-48ba-8ab8-0788ec7d2c96' User entered 'None (0)'	System	07 Sep 2020 01:53:16
	System	07 Sep 2020 01:53:16

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:56', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '722efe2b-a930-48ba-8ab8-0788ec7d2c96' User entered 'None (0)'	System	07 Sep 2020 01:53:16
	System	07 Sep 2020 01:53:16

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:52:59', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '722efe2b-a930-48ba-8ab8-0788ec7d2c96'	System	07 Sep 2020 01:53:16
User entered 'None (0)'	System	07 Sep 2020 01:53:16

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:53:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '722efe2b-a930-48ba-8ab8-0788ec7d2c96'	System	07 Sep 2020 01:53:16
User entered 'None (0)'	System	07 Sep 2020 01:53:16

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:53:05', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '722efe2b-a930-48ba-8ab8-0788ec7d2c96'	System	07 Sep 2020 01:53:16
User entered 'No (N)'	System	07 Sep 2020 01:53:16

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-06T21:53:15', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '722efe2b-a930-48ba-8ab8-0788ec7d2c96' User entered '06 Sep 2020 21:53'	System	07 Sep 2020 01:53:16
	System	07 Sep 2020 01:53:16

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 5'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:25', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '710234f0-5a73-44c9-88b7-2917f147db1c' User entered 'None (0)'	System	08 Sep 2020 15:36:55
	System	08 Sep 2020 15:36:55

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '710234f0-5a73-44c9-88b7-2917f147db1c' User entered 'None (0)'	System	08 Sep 2020 15:36:55
	System	08 Sep 2020 15:36:55

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:29', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '710234f0-5a73-44c9-88b7-2917f147db1c' User entered 'None (0)'	System	08 Sep 2020 15:36:55
	System	08 Sep 2020 15:36:55

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:32', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '710234f0-5a73-44c9-88b7-2917f147db1c' User entered 'None (0)'	System	08 Sep 2020 15:36:55
	System	08 Sep 2020 15:36:55

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '710234f0-5a73-44c9-88b7-2917f147db1c' User entered 'None (0)'	System	08 Sep 2020 15:36:55
	System	08 Sep 2020 15:36:55

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '710234f0-5a73-44c9-88b7-2917f147db1c' User entered 'None (0)'	System	08 Sep 2020 15:36:55
	System	08 Sep 2020 15:36:55

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '710234f0-5a73-44c9-88b7-2917f147db1c' User entered 'No (N)'	System	08 Sep 2020 15:36:55
	System	08 Sep 2020 15:36:55

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T11:36:51', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '710234f0-5a73-44c9-88b7-2917f147db1c' User entered '08 Sep 2020 11:36'	System	08 Sep 2020 15:36:55
	System	08 Sep 2020 15:36:55

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 6'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:36:35', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f7c0b902-8f29-410e-aa1c-40fa74812d9a' User entered 'None (0)'	System	09 Sep 2020 02:37:34
	System	09 Sep 2020 02:37:34

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:36:40', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f7c0b902-8f29-410e-aa1c-40fa74812d9a' User entered 'None (0)'	System	09 Sep 2020 02:37:34
	System	09 Sep 2020 02:37:34

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:37:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f7c0b902-8f29-410e-aa1c-40fa74812d9a' User entered 'None (0)'	System	09 Sep 2020 02:37:34
	System	09 Sep 2020 02:37:34

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:37:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f7c0b902-8f29-410e-aa1c-40fa74812d9a' User entered 'None (0)'	System	09 Sep 2020 02:37:34
	System	09 Sep 2020 02:37:34

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:37:11', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f7c0b902-8f29-410e-aa1c-40fa74812d9a' User entered 'None (0)'	System	09 Sep 2020 02:37:34
	System	09 Sep 2020 02:37:34

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:37:18', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f7c0b902-8f29-410e-aa1c-40fa74812d9a' User entered 'None (0)'	System	09 Sep 2020 02:37:34
	System	09 Sep 2020 02:37:34

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:37:21', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f7c0b902-8f29-410e-aa1c-40fa74812d9a'	System	09 Sep 2020 02:37:34
User entered 'No (N)'	System	09 Sep 2020 02:37:34

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-08T22:37:30', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f7c0b902-8f29-410e-aa1c-40fa74812d9a' User entered '08 Sep 2020 22:37'	System	09 Sep 2020 02:37:34
	System	09 Sep 2020 02:37:34

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 7'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:53', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '47095919-d111-4615-80e7-5641b64d8b36'	System	10 Sep 2020 02:58:36
User entered 'None (0)'	System	10 Sep 2020 02:58:36

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:57:57', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '47095919-d111-4615-80e7-5641b64d8b36' User entered 'None (0)'	System	10 Sep 2020 02:58:36
	System	10 Sep 2020 02:58:36

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:58:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '47095919-d111-4615-80e7-5641b64d8b36'	System	10 Sep 2020 02:58:36
User entered 'None (0)'	System	10 Sep 2020 02:58:36

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:58:05', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '47095919-d111-4615-80e7-5641b64d8b36' User entered 'None (0)'	System	10 Sep 2020 02:58:36
	System	10 Sep 2020 02:58:36

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:58:10', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '47095919-d111-4615-80e7-5641b64d8b36' User entered 'None (0)'	System	10 Sep 2020 02:58:36
	System	10 Sep 2020 02:58:36

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:58:19', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '47095919-d111-4615-80e7-5641b64d8b36'	System	10 Sep 2020 02:58:36
User entered 'None (0)'	System	10 Sep 2020 02:58:36

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:58:24', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '47095919-d111-4615-80e7-5641b64d8b36'	System	10 Sep 2020 02:58:36
User entered 'No (N)'	System	10 Sep 2020 02:58:36

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-09T22:58:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '47095919-d111-4615-80e7-5641b64d8b36'	System	10 Sep 2020 02:58:36
User entered '09 Sep 2020 22:58'	System	10 Sep 2020 02:58:36

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	09 Sep 2020 02:36:04
User entered 'Day 8'	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-10T21:55:07', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '61781cef-1b26-4f8c-8ced-bae5fbf44d52'	System	11 Sep 2020 01:55:18
User entered 'No (N)'	System	11 Sep 2020 01:55:18

US3532231

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-09-10T21:55:16', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '61781cef-1b26-4f8c-8ced-bae5fbf44d52'	System	11 Sep 2020 01:55:18
User entered '10 Sep 2020 21:55'	System	11 Sep 2020 01:55:18

US3532231

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 02:36:04

US3532231

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 02:36:04

US3532231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	11 Sep 2020 20:36:02

US3532231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '11 Sep 2020'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	11 Sep 2020 20:36:02

US3532231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	11 Sep 2020 20:36:02

US3532231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	11 Sep 2020 20:36:02

US3532231

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	11 Sep 2020 20:36:09

US3532231

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'I'	System	11 Sep 2020 20:36:09

US3532231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	19 Sep 2020 18:55:02

US3532231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '19 Sep 2020'	Cindy Lubbers (b) (4)	19 Sep 2020 18:55:02

US3532231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	19 Sep 2020 18:55:02

US3532231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	Cindy Lubbers (b) (4)	19 Sep 2020 18:55:02

US3532231

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	19 Sep 2020 18:55:07

US3532231

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'I'	System	19 Sep 2020 18:55:07

US3532231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 15:15:34

US3532231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '26 Sep 2020'	Cindy Lubbers (b) (4)	26 Sep 2020 15:15:34

US3532231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 15:15:34

US3532231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	26 Sep 2020 15:15:34

US3532231

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	26 Sep 2020 15:15:40

US3532231

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'I'	System	26 Sep 2020 15:15:40

US3532231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Oct 2020 14:23:03

US3532231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '1 Oct 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 14:23:03

US3532231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	01 Oct 2020 14:23:03

US3532231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'VISIT2'	System	01 Oct 2020 14:23:03

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User accepted default value 'Pre-Dose (PREDOSE)'	Cindy Lubbers (b) (4) (b) (4)	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '1 Oct 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:17:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:17:32
User entered '10:06' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:17:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered '1 Oct 2020 10:06'	System	01 Oct 2020 15:17:32
User entered empty.	System	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:17:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:17:32
User entered '97.4' F reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:17:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:17:32
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:17:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:17:32
User entered '58' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:17:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'bpm'	System	01 Oct 2020 15:17:32
User entered empty.	System	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:17:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:17:32
User entered '16' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:17:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'breaths/min'	System	01 Oct 2020 15:17:32
User entered empty.	System	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:17:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:17:32
User entered '104' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:17:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'mmHg'	System	01 Oct 2020 15:17:32
User entered empty.	System	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Per CDM: Thank you for the response.. Please indicate if CS/NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 07:21:55
Query 'Per CDM: Thank you for the response.. Please indicate if CS/NCS and report as AE, if appropriate. ' answered with 'NCS' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:36:17
User opened query 'Per CDM: Thank you for the response.. Please indicate if CS/NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 06:26:42
Query 'Per CDM: Thank you for the response.. Please indicate if CS/NCS and report as AE, if appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 06:25:56
User opened query 'Per CDM: Thank you for the response.. Please indicate if CS/NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 06:25:11
User closed query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 06:25:11
Query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 14:26:55
User opened query 'Per CDM: Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:07:26
Query 'Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' canceled (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:07:05
User opened query 'Response is noted; however, please advise if out of range value is either NCS or CS. If CS, please add the event to the adverse event form.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:06:54

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EAB) (1725)

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: Assessment is needed for out of range values per protocol. Please assess if CS or NCS and report and AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:06:54
Query 'Per CDM: Assessment is needed for out of range values per protocol. Please assess if CS or NCS and report and AE, if appropriate.' answered with 'PI aware' (Site from DM).	Cindy Lubbers (b) (4)	14 Oct 2020 19:39:50
User opened query 'Per CDM: Assessment is needed for out of range values per protocol. Please assess if CS or NCS and report and AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 04:31:20
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 04:21:03
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'PI aware' (Site from System).	Cindy Lubbers (b) (4)	01 Oct 2020 15:45:38
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		01 Oct 2020 15:17:32
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 15:17:32
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 15:17:32
User entered '58' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:17:32
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 14:24:33
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'mmHg'	System	01 Oct 2020 15:17:32
User entered empty.	System	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User accepted default value 'Post-Dose (POSTDOSE)'	Cindy Lubbers (b) (4) (b) (4)	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '1 Oct 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:45:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:45:17
User entered '11:40' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:45:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered '1 Oct 2020 11:40'	System	01 Oct 2020 15:45:17
User entered empty.	System	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:45:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:45:17
User entered '97.7' F reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:45:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:45:17
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:45:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:45:17
User entered '55' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:45:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'bpm'	System	01 Oct 2020 15:45:17
User entered empty.	System	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:45:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:45:17
User entered '16' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:45:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'breaths/min'	System	01 Oct 2020 15:45:17
User entered empty.	System	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:45:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:45:17
User entered '129' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:45:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'mmHg'	System	01 Oct 2020 15:45:17
User entered empty.	System	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:45:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 15:45:17
User entered '67' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	01 Oct 2020 15:45:17
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 14:24:33
User entered empty.	System	01 Oct 2020 14:24:33
	Cindy Lubbers (b) (4)	01 Oct 2020 14:24:33
	(b) (4)	

US3532231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'mmHg'	System	01 Oct 2020 15:45:17
User entered empty.	System	01 Oct 2020 14:24:33

US3532231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Oct 2020 14:31:49

US3532231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '1 Oct 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 14:31:49

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

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)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '1 Oct 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '11:08'	Cindy Lubbers (b) (4)	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered '1 Oct 2020 11:08'	System	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Left Arm (LEFT ARM)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'ONCE'	System	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:05:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 15:26:57

US3532231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:18:08

US3532231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '1 Oct 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 15:18:08

US3532231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '10:45'	Cindy Lubbers (b) (4)	01 Oct 2020 15:18:08

US3532231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered '1 Oct 2020 10:45'	System	01 Oct 2020 15:18:08

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:05:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '1 Oct 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:05:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cindy Lubbers (b) (4) (b) (4)	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:05:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '10:40'	Cindy Lubbers (b) (4)	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered '1 Oct 2020 10:40'	System	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:05:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cindy Lubbers (b) (4) (b) (4)	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:05:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered empty.	System	01 Oct 2020 15:18:46

US3532231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:19:02

US3532231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'I'	System	01 Oct 2020 15:19:02

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8e6901f3-3b0a-4808-afe7-07a7240ae615' User entered 'Yes (Y)'	System	01 Oct 2020 15:41:26
	System	01 Oct 2020 15:41:26

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:13', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8e6901f3-3b0a-4808-afe7-07a7240ae615' User entered '97.7'	System	01 Oct 2020 15:41:26
	System	01 Oct 2020 15:41:26

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:18', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8e6901f3-3b0a-4808-afe7-07a7240ae615'	System	01 Oct 2020 15:41:26
User entered 'No (N)'	System	01 Oct 2020 15:41:26

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:24', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8e6901f3-3b0a-4808-afe7-07a7240ae615' User entered '01 Oct 2020 11:41'	System	01 Oct 2020 15:41:26
	System	01 Oct 2020 15:41:26

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 11:28'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 13:58'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:27:13', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b4b0e6bb-5a93-4067-82fa-d72cf389e641' User entered 'Yes (Y)'	System	02 Oct 2020 02:28:08
	System	02 Oct 2020 02:28:08

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:27:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b4b0e6bb-5a93-4067-82fa-d72cf389e641' User entered '97.0'	System	02 Oct 2020 02:28:08
	System	02 Oct 2020 02:28:08

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:27:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b4b0e6bb-5a93-4067-82fa-d72cf389e641' User entered 'No (N)'	System	02 Oct 2020 02:28:08
	System	02 Oct 2020 02:28:08

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:28:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b4b0e6bb-5a93-4067-82fa-d72cf389e641' User entered '01 Oct 2020 22:28'	System	02 Oct 2020 02:28:08
	System	02 Oct 2020 02:28:08

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 14:53'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 2'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:20:28', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '19700295-6f10-4dfc-8b0d-a2a6e7dd24b0' User entered 'Yes (Y)'	System	03 Oct 2020 00:20:57
	System	03 Oct 2020 00:20:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:20:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '19700295-6f10-4dfc-8b0d-a2a6e7dd24b0' User entered '96.9'	System	03 Oct 2020 00:20:57
	System	03 Oct 2020 00:20:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:20:43', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '19700295-6f10-4dfc-8b0d-a2a6e7dd24b0'	System	03 Oct 2020 00:20:57
User entered 'No (N)'	System	03 Oct 2020 00:20:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:20:52', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '19700295-6f10-4dfc-8b0d-a2a6e7dd24b0' User entered '02 Oct 2020 20:20'	System	03 Oct 2020 00:20:57
	System	03 Oct 2020 00:20:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 3'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:56:14', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f26f2dcd-5318-4e1d-9bd9-4aaab33d757b' User entered 'Yes (Y)'	System	04 Oct 2020 02:59:21
	System	04 Oct 2020 02:59:21

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:58:56', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f26f2dcd-5318-4e1d-9bd9-4aaab33d757b' User entered '95.7'	System	04 Oct 2020 02:59:21
	System	04 Oct 2020 02:59:21

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:01', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f26f2dcd-5318-4e1d-9bd9-4aaab33d757b'	System	04 Oct 2020 02:59:21
User entered 'Yes (Y)'	System	04 Oct 2020 02:59:21

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
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 'Acetaminophen for pain' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 03:56:27
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.'	Cindy Lubbers (b) (4)	08 Oct 2020 19:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f26f2dcd-5318-4e1d-9bd9-4aaab33d757b'	(b) (4)	
User entered '1'	System	04 Oct 2020 02:59:21
	System	04 Oct 2020 02:59:21
	System	04 Oct 2020 02:59:21

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f26f2dcd-5318-4e1d-9bd9-4aaab33d757b' User entered '0'	System	04 Oct 2020 02:59:21
	System	04 Oct 2020 02:59:21

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:18', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f26f2dcd-5318-4e1d-9bd9-4aaab33d757b' User entered '03 Oct 2020 22:59'	System	04 Oct 2020 02:59:21
	System	04 Oct 2020 02:59:21

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 4'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:02:18', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555dc998-ea4a-486a-ba78-9c7b74d49976' User entered 'Yes (Y)'	System	05 Oct 2020 03:02:52
	System	05 Oct 2020 03:02:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:02:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555dc998-ea4a-486a-ba78-9c7b74d49976' User entered '97.0'	System	05 Oct 2020 03:02:52
	System	05 Oct 2020 03:02:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:02:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555dc998-ea4a-486a-ba78-9c7b74d49976' User entered 'Yes (Y)'	System	05 Oct 2020 03:02:52
	System	05 Oct 2020 03:02:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
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 'Acetaminophen for pain' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 03:57:57
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.'	Cindy Lubbers (b) (4)	08 Oct 2020 19:13:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:02:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555dc998-ea4a-486a-ba78-9c7b74d49976'	(b) (4)	
User entered '1'	System	05 Oct 2020 03:02:52
	System	05 Oct 2020 03:02:52
	System	05 Oct 2020 03:02:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:02:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555dc998-ea4a-486a-ba78-9c7b74d49976' User entered '0'	System	05 Oct 2020 03:02:52
	System	05 Oct 2020 03:02:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:02:49', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555dc998-ea4a-486a-ba78-9c7b74d49976' User entered '04 Oct 2020 23:02'	System	05 Oct 2020 03:02:52
	System	05 Oct 2020 03:02:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 5'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:18:28', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ca56a2be-eb74-4ebb-9bc2-6ca77d9f77e1' User entered 'Yes (Y)'	System	06 Oct 2020 01:19:50
	System	06 Oct 2020 01:19:50

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:18:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ca56a2be-eb74-4ebb-9bc2-6ca77d9f77e1' User entered '98.9'	System	06 Oct 2020 01:19:50
	System	06 Oct 2020 01:19:50

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:19:28', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ca56a2be-eb74-4ebb-9bc2-6ca77d9f77e1' User entered 'Yes (Y)'	System	06 Oct 2020 01:19:50
	System	06 Oct 2020 01:19:50

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
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 'Acetaminophen for pain' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 03:58:15
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.'	Cindy Lubbers (b) (4)	08 Oct 2020 19:13:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:19:32', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ca56a2be-eb74-4ebb-9bc2-6ca77d9f77e1'	(b) (4)	
User entered '1'	System	06 Oct 2020 01:19:50
	System	06 Oct 2020 01:19:50
	System	06 Oct 2020 01:19:50

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:19:32', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ca56a2be-eb74-4ebb-9bc2-6ca77d9f77e1' User entered '0'	System	06 Oct 2020 01:19:50
	System	06 Oct 2020 01:19:50

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:19:47', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ca56a2be-eb74-4ebb-9bc2-6ca77d9f77e1' User entered '05 Oct 2020 21:19'	System	06 Oct 2020 01:19:50
	System	06 Oct 2020 01:19:50

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 6'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:14:56', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6d0d8cda-cb17-4070-b2fa-b3a0d60e1fbc' User entered 'Yes (Y)'	System	07 Oct 2020 02:15:16
	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:14:15', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6d0d8cda-cb17-4070-b2fa-b3a0d60e1fbc' User entered '101.6'	System	07 Oct 2020 02:15:16
	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:14:40', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6d0d8cda-cb17-4070-b2fa-b3a0d60e1fbc'	System	07 Oct 2020 02:15:16
User entered 'Yes (Y)'	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
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 'Ibuprofen for fever' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 05:41:36
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.'	Cindy Lubbers (b) (4)	08 Oct 2020 19:13:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:14:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6d0d8cda-cb17-4070-b2fa-b3a0d60e1fbc'	(b) (4)	
User entered '1'	System	07 Oct 2020 02:15:16
	System	07 Oct 2020 02:15:16
	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:14:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6d0d8cda-cb17-4070-b2fa-b3a0d60e1fbc' User entered '0'	System	07 Oct 2020 02:15:16
	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:15:14', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '6d0d8cda-cb17-4070-b2fa-b3a0d60e1fbc' User entered '06 Oct 2020 22:15'	System	07 Oct 2020 02:15:16
	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 7'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:21:14', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f991eea5-6eaa-463e-b64d-ca3ecf16f0df' User entered 'No (N)'	System	08 Oct 2020 03:21:52
	System	08 Oct 2020 03:21:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:21:19', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f991eea5-6eaa-463e-b64d-ca3ecf16f0df' User entered 'Yes (Y)'	System	08 Oct 2020 03:21:52
	System	08 Oct 2020 03:21:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
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 'Acetaminophen for pain/fever' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 03:55:26
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.'	Cindy Lubbers (b) (4)	08 Oct 2020 19:15:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:21:31', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f991eea5-6eaa-463e-b64d-ca3ecf16f0df'	(b) (4)	
User entered '1'	System	08 Oct 2020 03:21:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Acetaminophen to prevent pain/fever' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 03:55:29
User opened query 'Per the participant response, medication was taken to prevent 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).	Cindy Lubbers (b) (4)	08 Oct 2020 19:15:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:21:31', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f991eea5-6eaa-463e-b64d-ca3ecf16f0df'	(b) (4)	
User entered '1'	System	08 Oct 2020 03:21:52
	System	08 Oct 2020 03:21:52
	System	08 Oct 2020 03:21:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:21:49', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f991eea5-6eaa-463e-b64d-ca3ecf16f0df' User entered '07 Oct 2020 23:21'	System	08 Oct 2020 03:21:52
	System	08 Oct 2020 03:21:52

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	07 Oct 2020 02:15:16
User entered 'Day 8'	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T22:59:17', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e652e087-f0cb-4a91-b5c8-6a0f7e478b44'	System	09 Oct 2020 02:59:48
User entered 'Yes (Y)'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T22:59:25', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e652e087-f0cb-4a91-b5c8-6a0f7e478b44' User entered '99.6'	System	09 Oct 2020 02:59:48
	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T22:59:31', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e652e087-f0cb-4a91-b5c8-6a0f7e478b44'	System	09 Oct 2020 02:59:48
User entered 'Yes (Y)'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T22:59:35', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e652e087-f0cb-4a91-b5c8-6a0f7e478b44'	System	09 Oct 2020 02:59:48
User entered '0'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'fever and pain' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 07:13:51
User opened query 'Per the participant response, medication was taken to prevent 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).	Cindy Lubbers (b) (4)	29 Oct 2020 15:46:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T22:59:35', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e652e087-f0cb-4a91-b5c8-6a0f7e478b44'	(b) (4)	
User entered '1'	System	09 Oct 2020 02:59:48
	System	09 Oct 2020 02:59:48
	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T22:59:45', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e652e087-f0cb-4a91-b5c8-6a0f7e478b44'	System	09 Oct 2020 02:59:48
User entered '08 Oct 2020 22:59'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	09 Oct 2020 02:59:48
User entered 'Day 9'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 12:00'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	09 Oct 2020 02:59:48
User entered 'Day 10'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:32', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b9fc9f3c-0753-4e67-89af-02a6948b99f0' User entered 'None (1)'	System	01 Oct 2020 15:41:55
	System	01 Oct 2020 15:41:55

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:36', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b9fc9f3c-0753-4e67-89af-02a6948b99f0' User entered 'No (N)'	System	01 Oct 2020 15:41:55
	System	01 Oct 2020 15:41:55

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b9fc9f3c-0753-4e67-89af-02a6948b99f0' User entered 'No (N)'	System	01 Oct 2020 15:41:55
	System	01 Oct 2020 15:41:55

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b9fc9f3c-0753-4e67-89af-02a6948b99f0' User entered 'None (1)'	System	01 Oct 2020 15:41:55
	System	01 Oct 2020 15:41:55

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:41:53', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b9fc9f3c-0753-4e67-89af-02a6948b99f0' User entered '01 Oct 2020 11:41'	System	01 Oct 2020 15:41:55
	System	01 Oct 2020 15:41:55

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 11:28'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 13:58'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:28:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '171ce652-678c-4d2b-9d73-b9a54e592205'	System	02 Oct 2020 02:29:49
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 02:29:49

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:29:15', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '171ce652-678c-4d2b-9d73-b9a54e592205' User entered 'No (N)'	System	02 Oct 2020 02:29:49
	System	02 Oct 2020 02:29:49

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:29:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '171ce652-678c-4d2b-9d73-b9a54e592205' User entered 'No (N)'	System	02 Oct 2020 02:29:49
	System	02 Oct 2020 02:29:49

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:29:33', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '171ce652-678c-4d2b-9d73-b9a54e592205'	System	02 Oct 2020 02:29:49
User entered 'None (1)'	System	02 Oct 2020 02:29:49

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:29:47', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '171ce652-678c-4d2b-9d73-b9a54e592205' User entered '01 Oct 2020 22:29'	System	02 Oct 2020 02:29:49
	System	02 Oct 2020 02:29:49

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 14:53'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 2'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:21:18', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aac99d04-e56c-4132-a330-b5a00577d19e'	System	03 Oct 2020 00:21:43
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 00:21:43

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:21:22', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aac99d04-e56c-4132-a330-b5a00577d19e' User entered 'No (N)'	System	03 Oct 2020 00:21:43
	System	03 Oct 2020 00:21:43

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:21:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aac99d04-e56c-4132-a330-b5a00577d19e' User entered 'No (N)'	System	03 Oct 2020 00:21:43
	System	03 Oct 2020 00:21:43

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:21:30', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aac99d04-e56c-4132-a330-b5a00577d19e'	System	03 Oct 2020 00:21:43
User entered 'None (1)'	System	03 Oct 2020 00:21:43

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:21:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aac99d04-e56c-4132-a330-b5a00577d19e' User entered '02 Oct 2020 20:21'	System	03 Oct 2020 00:21:43
	System	03 Oct 2020 00:21:43

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 3'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:25', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '49ea6269-07a2-4bb5-a583-6e9c372a1a86'	System	04 Oct 2020 02:59:57
User entered 'None (1)'	System	04 Oct 2020 02:59:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '49ea6269-07a2-4bb5-a583-6e9c372a1a86'	System	04 Oct 2020 02:59:57
User entered 'No (N)'	System	04 Oct 2020 02:59:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:45', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '49ea6269-07a2-4bb5-a583-6e9c372a1a86' User entered 'No (N)'	System	04 Oct 2020 02:59:57
	System	04 Oct 2020 02:59:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:48', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '49ea6269-07a2-4bb5-a583-6e9c372a1a86'	System	04 Oct 2020 02:59:57
User entered 'None (1)'	System	04 Oct 2020 02:59:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T22:59:55', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '49ea6269-07a2-4bb5-a583-6e9c372a1a86' User entered '03 Oct 2020 22:59'	System	04 Oct 2020 02:59:57
	System	04 Oct 2020 02:59:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 4'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:03:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1d525b92-a59e-4446-a844-5116f6771f66'	System	05 Oct 2020 03:03:51
User entered 'None (1)'	System	05 Oct 2020 03:03:51

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:03:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1d525b92-a59e-4446-a844-5116f6771f66'	System	05 Oct 2020 03:03:51
User entered 'No (N)'	System	05 Oct 2020 03:03:51

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:03:09', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1d525b92-a59e-4446-a844-5116f6771f66'	System	05 Oct 2020 03:03:51
User entered 'No (N)'	System	05 Oct 2020 03:03:51

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:03:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1d525b92-a59e-4446-a844-5116f6771f66'	System	05 Oct 2020 03:03:51
User entered 'None (1)'	System	05 Oct 2020 03:03:51

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:03:48', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1d525b92-a59e-4446-a844-5116f6771f66' User entered '04 Oct 2020 23:03'	System	05 Oct 2020 03:03:51
	System	05 Oct 2020 03:03:51

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 5'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:19:56', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7a77b795-9fec-4143-ba60-10c615c513bb'	System	06 Oct 2020 01:20:44
User entered 'Does not interfere with activity (2)'	System	06 Oct 2020 01:20:44

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:20:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7a77b795-9fec-4143-ba60-10c615c513bb' User entered 'No (N)'	System	06 Oct 2020 01:20:44
	System	06 Oct 2020 01:20:44

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:20:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7a77b795-9fec-4143-ba60-10c615c513bb' User entered 'No (N)'	System	06 Oct 2020 01:20:44
	System	06 Oct 2020 01:20:44

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:20:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7a77b795-9fec-4143-ba60-10c615c513bb' User entered 'None (1)'	System	06 Oct 2020 01:20:44
	System	06 Oct 2020 01:20:44

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:20:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '7a77b795-9fec-4143-ba60-10c615c513bb' User entered '05 Oct 2020 21:20'	System	06 Oct 2020 01:20:44
	System	06 Oct 2020 01:20:44

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 6'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:15:37', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ac3ea633-3727-4cf0-af67-c97ef4a4705e' User entered 'None (1)'	System	07 Oct 2020 02:16:15
	System	07 Oct 2020 02:16:15

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:15:41', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ac3ea633-3727-4cf0-af67-c97ef4a4705e' User entered 'No (N)'	System	07 Oct 2020 02:16:15
	System	07 Oct 2020 02:16:15

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:15:45', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ac3ea633-3727-4cf0-af67-c97ef4a4705e' User entered 'No (N)'	System	07 Oct 2020 02:16:15
	System	07 Oct 2020 02:16:15

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:16:01', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ac3ea633-3727-4cf0-af67-c97ef4a4705e'	System	07 Oct 2020 02:16:15
User entered 'None (1)'	System	07 Oct 2020 02:16:15

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:16:14', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'ac3ea633-3727-4cf0-af67-c97ef4a4705e' User entered '06 Oct 2020 22:16'	System	07 Oct 2020 02:16:15
	System	07 Oct 2020 02:16:15

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 7'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:21:57', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555e97f0-81f9-46c0-98a8-bad1a080d545'	System	08 Oct 2020 03:22:28
User entered 'None (1)'	System	08 Oct 2020 03:22:28

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:22:01', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555e97f0-81f9-46c0-98a8-bad1a080d545'	System	08 Oct 2020 03:22:28
User entered 'No (N)'	System	08 Oct 2020 03:22:28

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:22:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555e97f0-81f9-46c0-98a8-bad1a080d545'	System	08 Oct 2020 03:22:28
User entered 'No (N)'	System	08 Oct 2020 03:22:28

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:22:12', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555e97f0-81f9-46c0-98a8-bad1a080d545'	System	08 Oct 2020 03:22:28
User entered 'None (1)'	System	08 Oct 2020 03:22:28

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:22:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '555e97f0-81f9-46c0-98a8-bad1a080d545' User entered '07 Oct 2020 23:22'	System	08 Oct 2020 03:22:28
	System	08 Oct 2020 03:22:28

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:42:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'fb5e6947-9ebe-4514-bd5b-5d8846ba270d' User entered 'None (0)'	System	01 Oct 2020 15:42:41
	System	01 Oct 2020 15:42:41

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:42:09', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'fb5e6947-9ebe-4514-bd5b-5d8846ba270d' User entered 'None (0)'	System	01 Oct 2020 15:42:41
	System	01 Oct 2020 15:42:41

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:42:12', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'fb5e6947-9ebe-4514-bd5b-5d8846ba270d' User entered 'None (0)'	System	01 Oct 2020 15:42:41
	System	01 Oct 2020 15:42:41

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:42:15', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'fb5e6947-9ebe-4514-bd5b-5d8846ba270d' User entered 'None (0)'	System	01 Oct 2020 15:42:41
	System	01 Oct 2020 15:42:41

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:42:17', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'fb5e6947-9ebe-4514-bd5b-5d8846ba270d' User entered 'None (0)'	System	01 Oct 2020 15:42:41
	System	01 Oct 2020 15:42:41

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:42:22', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'fb5e6947-9ebe-4514-bd5b-5d8846ba270d' User entered 'None (0)'	System	01 Oct 2020 15:42:41
	System	01 Oct 2020 15:42:41

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:42:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'fb5e6947-9ebe-4514-bd5b-5d8846ba270d' User entered 'No (N)'	System	01 Oct 2020 15:42:41
	System	01 Oct 2020 15:42:41

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T11:42:37', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'fb5e6947-9ebe-4514-bd5b-5d8846ba270d' User entered '01 Oct 2020 11:42'	System	01 Oct 2020 15:42:41
	System	01 Oct 2020 15:42:41

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 11:28'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 13:58'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:29:56', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '798511ff-37e6-4f2b-8ad6-db6a987f13f6' User entered 'None (0)'	System	02 Oct 2020 02:31:32
	System	02 Oct 2020 02:31:32

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:30:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '798511ff-37e6-4f2b-8ad6-db6a987f13f6' User entered 'None (0)'	System	02 Oct 2020 02:31:32
	System	02 Oct 2020 02:31:32

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:30:47', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '798511ff-37e6-4f2b-8ad6-db6a987f13f6'	System	02 Oct 2020 02:31:32
User entered 'No interference with activity (1)'	System	02 Oct 2020 02:31:32

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:30:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '798511ff-37e6-4f2b-8ad6-db6a987f13f6'	System	02 Oct 2020 02:31:32
User entered 'No interference with activity (1)'	System	02 Oct 2020 02:31:32

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:30:56', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '798511ff-37e6-4f2b-8ad6-db6a987f13f6' User entered 'None (0)'	System	02 Oct 2020 02:31:32
	System	02 Oct 2020 02:31:32

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:31:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '798511ff-37e6-4f2b-8ad6-db6a987f13f6' User entered 'None (0)'	System	02 Oct 2020 02:31:32
	System	02 Oct 2020 02:31:32

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:31:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '798511ff-37e6-4f2b-8ad6-db6a987f13f6' User entered 'No (N)'	System	02 Oct 2020 02:31:32
	System	02 Oct 2020 02:31:32

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-01T22:31:29', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '798511ff-37e6-4f2b-8ad6-db6a987f13f6' User entered '01 Oct 2020 22:31'	System	02 Oct 2020 02:31:32
	System	02 Oct 2020 02:31:32

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '01 Oct 2020 14:53'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 2'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:21:48', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5688cc49-b886-45ce-8b35-da8a24556117' User entered 'None (0)'	System	03 Oct 2020 00:23:14
	System	03 Oct 2020 00:23:14

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:22:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5688cc49-b886-45ce-8b35-da8a24556117'	System	03 Oct 2020 00:23:14
User entered 'No interference with activity (1)'	System	03 Oct 2020 00:23:14

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:22:12', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5688cc49-b886-45ce-8b35-da8a24556117'	System	03 Oct 2020 00:23:14
User entered 'Some interference with activity (2)'	System	03 Oct 2020 00:23:14

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:22:18', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5688cc49-b886-45ce-8b35-da8a24556117'	System	03 Oct 2020 00:23:14
User entered 'Some interference with activity (2)'	System	03 Oct 2020 00:23:14

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:22:21', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5688cc49-b886-45ce-8b35-da8a24556117' User entered 'None (0)'	System	03 Oct 2020 00:23:14
	System	03 Oct 2020 00:23:14

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:22:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5688cc49-b886-45ce-8b35-da8a24556117' User entered 'None (0)'	System	03 Oct 2020 00:23:14
	System	03 Oct 2020 00:23:14

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:22:30', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5688cc49-b886-45ce-8b35-da8a24556117' User entered 'No (N)'	System	03 Oct 2020 00:23:14
	System	03 Oct 2020 00:23:14

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-02T20:22:56', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5688cc49-b886-45ce-8b35-da8a24556117' User entered '02 Oct 2020 20:22'	System	03 Oct 2020 00:23:14
	System	03 Oct 2020 00:23:14

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 3'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T23:00:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b4f84c8-fa95-4a04-81d3-7e286cc4d15d' User entered 'None (0)'	System	04 Oct 2020 03:01:38
	System	04 Oct 2020 03:01:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T23:00:08', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b4f84c8-fa95-4a04-81d3-7e286cc4d15d'	System	04 Oct 2020 03:01:38
User entered 'Some interference with activity (2)'	System	04 Oct 2020 03:01:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T23:01:30', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b4f84c8-fa95-4a04-81d3-7e286cc4d15d'	System	04 Oct 2020 03:01:38
User entered 'Some interference with activity (2)'	System	04 Oct 2020 03:01:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T23:00:28', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b4f84c8-fa95-4a04-81d3-7e286cc4d15d'	System	04 Oct 2020 03:01:38
User entered 'No interference with activity (1)'	System	04 Oct 2020 03:01:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T23:00:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b4f84c8-fa95-4a04-81d3-7e286cc4d15d' User entered 'None (0)'	System	04 Oct 2020 03:01:38
	System	04 Oct 2020 03:01:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T23:00:45', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b4f84c8-fa95-4a04-81d3-7e286cc4d15d' User entered 'None (0)'	System	04 Oct 2020 03:01:38
	System	04 Oct 2020 03:01:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T23:00:49', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b4f84c8-fa95-4a04-81d3-7e286cc4d15d' User entered 'No (N)'	System	04 Oct 2020 03:01:38
	System	04 Oct 2020 03:01:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-03T23:01:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b4f84c8-fa95-4a04-81d3-7e286cc4d15d' User entered '03 Oct 2020 23:01'	System	04 Oct 2020 03:01:38
	System	04 Oct 2020 03:01:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 4'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:03:55', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd0b42175-3e40-4b89-859f-c8d0afb3df19' User entered 'None (0)'	System	05 Oct 2020 03:04:38
	System	05 Oct 2020 03:04:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:04:03', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd0b42175-3e40-4b89-859f-c8d0afb3df19' User entered 'None (0)'	System	05 Oct 2020 03:04:38
	System	05 Oct 2020 03:04:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:04:08', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd0b42175-3e40-4b89-859f-c8d0afb3df19'	System	05 Oct 2020 03:04:38
User entered 'No interference with activity (1)'	System	05 Oct 2020 03:04:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:04:12', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd0b42175-3e40-4b89-859f-c8d0afb3df19'	System	05 Oct 2020 03:04:38
User entered 'No interference with activity (1)'	System	05 Oct 2020 03:04:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:04:16', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd0b42175-3e40-4b89-859f-c8d0afb3df19' User entered 'None (0)'	System	05 Oct 2020 03:04:38
	System	05 Oct 2020 03:04:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:04:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd0b42175-3e40-4b89-859f-c8d0afb3df19' User entered 'None (0)'	System	05 Oct 2020 03:04:38
	System	05 Oct 2020 03:04:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:04:24', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd0b42175-3e40-4b89-859f-c8d0afb3df19' User entered 'No (N)'	System	05 Oct 2020 03:04:38
	System	05 Oct 2020 03:04:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-04T23:04:35', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd0b42175-3e40-4b89-859f-c8d0afb3df19' User entered '04 Oct 2020 23:04'	System	05 Oct 2020 03:04:38
	System	05 Oct 2020 03:04:38

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 5'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:20:48', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0e5b373f-250b-47e3-abae-7930dad71c73' User entered 'None (0)'	System	06 Oct 2020 01:22:51
	System	06 Oct 2020 01:22:51

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:21:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0e5b373f-250b-47e3-abae-7930dad71c73'	System	06 Oct 2020 01:22:51
User entered 'Some interference with activity (2)'	System	06 Oct 2020 01:22:51

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:21:13', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0e5b373f-250b-47e3-abae-7930dad71c73'	System	06 Oct 2020 01:22:51
User entered 'Some interference with activity (2)'	System	06 Oct 2020 01:22:51

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:21:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0e5b373f-250b-47e3-abae-7930dad71c73'	System	06 Oct 2020 01:22:51
User entered 'No interference with activity (1)'	System	06 Oct 2020 01:22:51

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:21:43', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0e5b373f-250b-47e3-abae-7930dad71c73' User entered 'None (0)'	System	06 Oct 2020 01:22:51
	System	06 Oct 2020 01:22:51

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:22:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0e5b373f-250b-47e3-abae-7930dad71c73'	System	06 Oct 2020 01:22:51
User entered 'No interference with activity (1)'	System	06 Oct 2020 01:22:51

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:22:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0e5b373f-250b-47e3-abae-7930dad71c73'	System	06 Oct 2020 01:22:51
User entered 'No (N)'	System	06 Oct 2020 01:22:51

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-05T21:22:47', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0e5b373f-250b-47e3-abae-7930dad71c73' User entered '05 Oct 2020 21:22'	System	06 Oct 2020 01:22:51
	System	06 Oct 2020 01:22:51

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 6'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:16:35', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'dec1e494-ce81-4c34-b91e-3d013e711c97'	System	07 Oct 2020 02:19:08
User entered 'No interference with activity (1)'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:17:42', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'dec1e494-ce81-4c34-b91e-3d013e711c97'	System	07 Oct 2020 02:19:08
User entered 'Some interference with activity (2)'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:17:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'dec1e494-ce81-4c34-b91e-3d013e711c97'	System	07 Oct 2020 02:19:08
User entered 'Some interference with activity (2)'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:17:55', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'dec1e494-ce81-4c34-b91e-3d013e711c97'	System	07 Oct 2020 02:19:08
User entered 'Some interference with activity (2)'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:17:59', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'dec1e494-ce81-4c34-b91e-3d013e711c97'	System	07 Oct 2020 02:19:08
User entered 'None (0)'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:18:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'dec1e494-ce81-4c34-b91e-3d013e711c97'	System	07 Oct 2020 02:19:08
User entered 'No interference with activity (1)'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:18:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'dec1e494-ce81-4c34-b91e-3d013e711c97'	System	07 Oct 2020 02:19:08
User entered 'Yes (Y)'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-06T22:19:05', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'dec1e494-ce81-4c34-b91e-3d013e711c97'	System	07 Oct 2020 02:19:08
User entered '06 Oct 2020 22:19'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	01 Oct 2020 15:26:57
User entered 'Day 7'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:22:46', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b6691e0-9437-440d-99ba-f3b55849c274' User entered 'None (0)'	System	08 Oct 2020 03:24:30
	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:22:51', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b6691e0-9437-440d-99ba-f3b55849c274'	System	08 Oct 2020 03:24:30
User entered 'Some interference with activity (2)'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:23:06', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b6691e0-9437-440d-99ba-f3b55849c274'	System	08 Oct 2020 03:24:30
User entered 'Some interference with activity (2)'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:23:12', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b6691e0-9437-440d-99ba-f3b55849c274'	System	08 Oct 2020 03:24:30
User entered 'Some interference with activity (2)'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:23:24', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b6691e0-9437-440d-99ba-f3b55849c274' User entered 'None (0)'	System	08 Oct 2020 03:24:30
	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:23:33', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b6691e0-9437-440d-99ba-f3b55849c274'	System	08 Oct 2020 03:24:30
User entered 'No interference with activity (1)'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:23:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b6691e0-9437-440d-99ba-f3b55849c274' User entered 'No (N)'	System	08 Oct 2020 03:24:30
	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-07T23:24:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '8b6691e0-9437-440d-99ba-f3b55849c274' User entered '07 Oct 2020 23:24'	System	08 Oct 2020 03:24:30
	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:26:57

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	07 Oct 2020 02:19:08
User entered 'Day 8'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:00:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '30a6e199-8287-4e1d-a937-88d18bb28264'	System	09 Oct 2020 03:00:46
User entered 'Significant; prevents daily activity (3)'	System	09 Oct 2020 03:00:46

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:00:42', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '30a6e199-8287-4e1d-a937-88d18bb28264' User entered '08 Oct 2020 23:00'	System	09 Oct 2020 03:00:46
	System	09 Oct 2020 03:00:46

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	08 Oct 2020 03:24:30
User entered 'Day 9'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	09 Oct 2020 03:00:46
User entered 'Day 10'	System	09 Oct 2020 03:00:46

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:00:46

US3532231

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:00:46

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	07 Oct 2020 02:19:08
User entered 'Day 8'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:00:59', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5d4b98ae-5d5b-464e-8e55-e8a66d96fb13'	System	09 Oct 2020 03:01:10
User entered 'No interference with activity (1)'	System	09 Oct 2020 03:01:10

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:01:05', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5d4b98ae-5d5b-464e-8e55-e8a66d96fb13' User entered '08 Oct 2020 23:01'	System	09 Oct 2020 03:01:10
	System	09 Oct 2020 03:01:10

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	08 Oct 2020 03:24:30
User entered 'Day 9'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:05:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	09 Oct 2020 03:01:10
User entered 'Day 10'	System	09 Oct 2020 03:01:10

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:05:38

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:01:10

US3532231

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:01:10

US3532231

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	07 Oct 2020 02:19:08
User entered 'Day 8'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:01:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '03cb109e-af5c-4f63-9d66-372b84b138a4' User entered 'None (0)'	System	09 Oct 2020 03:01:41
	System	09 Oct 2020 03:01:41

US3532231

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:01:37', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '03cb109e-af5c-4f63-9d66-372b84b138a4' User entered '08 Oct 2020 23:01'	System	09 Oct 2020 03:01:41
	System	09 Oct 2020 03:01:41

US3532231

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	07 Oct 2020 02:19:08
User entered 'Day 8'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:05:38

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:01:50', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f38c8f9a-a471-480b-914e-95613f4c73fe'	System	09 Oct 2020 03:01:59
User entered 'Some interference with activity not requiring medical attention (2)'	System	09 Oct 2020 03:01:59

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:19:08

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:01:54', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'f38c8f9a-a471-480b-914e-95613f4c73fe' User entered '08 Oct 2020 23:01'	System	09 Oct 2020 03:01:59
	System	09 Oct 2020 03:01:59

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	08 Oct 2020 03:24:30
User entered 'Day 9'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:05:38

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	09 Oct 2020 03:01:59
User entered 'Day 10'	System	09 Oct 2020 03:01:59

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:05:38

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 03:01:59

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 03:01:59

US3532231

Folder: Diary Dose 2 (1)

Form: Chills_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	07 Oct 2020 02:15:16
User entered 'Day 8'	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:02:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '3df7c547-188a-473e-a56f-f48b70b2438a' User entered 'Yes (Y)'	System	09 Oct 2020 03:02:13
	System	09 Oct 2020 03:02:13

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-10-08T23:02:09', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '3df7c547-188a-473e-a56f-f48b70b2438a' User entered '08 Oct 2020 23:02'	System	09 Oct 2020 03:02:13
	System	09 Oct 2020 03:02:13

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:15:16

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	08 Oct 2020 03:24:30
User entered 'Day 9'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 03:24:30

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	09 Oct 2020 02:59:48
User entered 'Day 10'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 02:59:48

US3532231

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:05:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 02:59:48

US3532231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	08 Oct 2020 18:46:04

US3532231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	11 Nov 2020 12:30:12
User entered '8 Oct 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	08 Oct 2020 18:46:04
	(b) (4)	

US3532231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	08 Oct 2020 18:46:04

US3532231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	08 Oct 2020 18:46:04

US3532231

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:07:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	08 Oct 2020 18:46:07

US3532231

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'I'	System	08 Oct 2020 18:46:07

US3532231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	
	System	16 Oct 2020 19:15:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	16 Oct 2020 19:15:05
	(b) (4)	
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	16 Oct 2020 19:14:33
User entered 'No (N)'	Cindy Lubbers (b) (4)	16 Oct 2020 19:14:33
	(b) (4)	

US3532231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	16 Oct 2020 19:15:05
User entered empty.	(b) (4)	
	Cindy Lubbers (b) (4)	16 Oct 2020 19:14:33
	(b) (4)	

US3532231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	Cindy Lubbers (b) (4)	16 Oct 2020 19:14:33

US3532231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Subject hospitalized. Per wife some confusion. Notes are in chart.'	Cindy Lubbers (b) (4)	16 Oct 2020 19:14:33

US3532231

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	16 Oct 2020 19:15:09

US3532231

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'I'	System	16 Oct 2020 19:15:09

US3532231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	23 Oct 2020 17:48:11

US3532231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '23 Oct 2020'	Cindy Lubbers (b) (4)	23 Oct 2020 17:48:11

US3532231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	23 Oct 2020 17:48:11

US3532231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	23 Oct 2020 17:48:11

US3532231

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	23 Oct 2020 17:48:15

US3532231

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'I'	System	23 Oct 2020 17:48:15

US3532231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:39:28

US3532231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '29 Oct 2020'	Cindy Lubbers (b) (4)	29 Oct 2020 16:39:28

US3532231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:39:28

US3532231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'VISIT3'	System	29 Oct 2020 16:39:28

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '29 Oct 2020'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '10:09'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered '29 Oct 2020 10:09'	System	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '97.2' F	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Oral (Oral)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '58'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'bpm'	System	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '16'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'breaths/min'	System	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '113'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'mmHg'	System	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '63'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'mmHg'	System	29 Oct 2020 16:40:24

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36

US3532231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36

US3532231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'No (N)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:29

US3532231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:29

US3532231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:47

US3532231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '29 Oct 2020'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:47

US3532231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered '10:18'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:47

US3532231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered '29 Oct 2020 10:18'	System	29 Oct 2020 16:40:47

US3532231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:22:04
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:40:56

US3532231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 01:59:36
User entered 'I'	System	29 Oct 2020 16:40:56

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 64'	System	03 Sep 2020 16:00:44

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:07:57', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered 'Yes (Y)'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:08:11', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered 'Yes (Y)'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:08:21', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'came in for COVID visit' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 05:26:46
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	01 Dec 2020 18:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:08:31', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered 'Yes (Y)'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered '1'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered '1'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered '1'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered '0'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered '1'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered '1'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered '1'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:26', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '0'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:33', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:40', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered 'Yes (Y)'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:10:47', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53'	System	04 Nov 2020 14:11:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-04T09:11:08', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'aa88d80d-d2da-4183-8551-c4a145cf1a53' User entered '04 Nov 2020 09:11:08'	System	04 Nov 2020 14:11:18
	System	04 Nov 2020 14:11:18

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 16:00:44

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 71'	System	03 Sep 2020 16:00:44

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-12T12:00:59', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5805f03a-aaa5-47ef-8eee-790b33b1db83'	System	12 Nov 2020 17:01:39
User entered 'No (N)'	System	12 Nov 2020 17:01:39

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-12T12:01:02', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5805f03a-aaa5-47ef-8eee-790b33b1db83'	System	12 Nov 2020 17:01:39
User entered 'No (N)'	System	12 Nov 2020 17:01:39

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-12T12:01:13', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '5805f03a-aaa5-47ef-8eee-790b33b1db83' User entered '12 Nov 2020 12:01:13'	System	12 Nov 2020 17:01:39
	System	12 Nov 2020 17:01:39

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 16:00:44

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered 'Day 78'	System	03 Sep 2020 16:00:44

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-17T07:50:57', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '20f6cf3c-1220-4308-bb40-b01dc12f3403' User entered 'No (N)'	System	17 Nov 2020 12:53:36
	System	17 Nov 2020 12:53:36

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-17T07:52:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '20f6cf3c-1220-4308-bb40-b01dc12f3403'	System	17 Nov 2020 12:53:36
User entered 'No (N)'	System	17 Nov 2020 12:53:36

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-17T07:53:30', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '20f6cf3c-1220-4308-bb40-b01dc12f3403' User entered '17 Nov 2020 07:53:30'	System	17 Nov 2020 12:53:36
	System	17 Nov 2020 12:53:36

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 16:00:44

US3532231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:39:39
Data entry locked.	System	03 Sep 2020 16:00:44
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 16:00:44

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-21T16:12:33', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1fcee81e-f0a6-42b5-8092-02fc2cad07a8' User entered 'No (N)'	System	21 Nov 2020 21:13:12

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-21T16:12:39', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1fcee81e-f0a6-42b5-8092-02fc2cad07a8' User entered 'No (N)'	System	21 Nov 2020 21:13:12

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-21T16:13:05', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1fcee81e-f0a6-42b5-8092-02fc2cad07a8' User entered '21 Nov 2020 16:13:05'	System	21 Nov 2020 21:13:12
	System	21 Nov 2020 21:13:12

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-28T00:02:20', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '233e5292-9bf3-4b63-8ffa-e353c0aa8424'	System	28 Nov 2020 05:03:41
User entered 'No (N)'	System	28 Nov 2020 05:03:41

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-28T00:02:25', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '233e5292-9bf3-4b63-8ffa-e353c0aa8424'	System	28 Nov 2020 05:03:41
User entered 'No (N)'	System	28 Nov 2020 05:03:41

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-11-28T00:02:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '233e5292-9bf3-4b63-8ffa-e353c0aa8424' User entered '28 Nov 2020 00:02:38'	System	28 Nov 2020 05:03:41
	System	28 Nov 2020 05:03:41

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-12-21T12:02:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a4373d3d-f331-4fae-ade6-13322dfb6dc3' User entered 'No (N)'	System	21 Dec 2020 17:02:50
	System	21 Dec 2020 17:02:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-12-21T12:01:14', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a4373d3d-f331-4fae-ade6-13322dfb6dc3' User entered 'No (N)'	System	21 Dec 2020 17:02:50
	System	21 Dec 2020 17:02:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-12-21T12:02:47', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'a4373d3d-f331-4fae-ade6-13322dfb6dc3' User entered '21 Dec 2020 12:02:47'	System	21 Dec 2020 17:02:50
	System	21 Dec 2020 17:02:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-12-29T18:34:21', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '530ef0f9-4544-4934-a52f-4a61c76f16ee' User entered 'No (N)'	System	29 Dec 2020 23:34:37
	System	29 Dec 2020 23:34:37

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-12-29T18:34:24', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '530ef0f9-4544-4934-a52f-4a61c76f16ee' User entered 'No (N)'	System	29 Dec 2020 23:34:37

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2020-12-29T18:34:35', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '530ef0f9-4544-4934-a52f-4a61c76f16ee' User entered '29 Dec 2020 18:34:35'	System	29 Dec 2020 23:34:37
	System	29 Dec 2020 23:34:37

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[New loss of taste](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[New loss of smell](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Sore throat](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Congestion](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Runny nose](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	05 Jan 2021 20:41:50

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-01-18T12:03:24', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b50297d1-ea9c-4a3d-a3c3-abe39eb46141' User entered 'No (N)'	System	18 Jan 2021 17:03:46
	System	18 Jan 2021 17:03:46

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-01-18T12:03:29', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b50297d1-ea9c-4a3d-a3c3-abe39eb46141' User entered 'No (N)'	System	18 Jan 2021 17:03:46

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-01-18T12:03:38', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b50297d1-ea9c-4a3d-a3c3-abe39eb46141' User entered '18 Jan 2021 12:03:38'	System	18 Jan 2021 17:03:46
	System	18 Jan 2021 17:03:46

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-01-23T08:03:40', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '58a71584-76d0-4127-ae57-1f0dc5c9c44d' User entered 'No (N)'	System	23 Jan 2021 13:04:08
	System	23 Jan 2021 13:04:08

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-01-23T08:03:48', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '58a71584-76d0-4127-ae57-1f0dc5c9c44d' User entered 'No (N)'	System	23 Jan 2021 13:04:08
	System	23 Jan 2021 13:04:08

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-01-23T08:04:04', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '58a71584-76d0-4127-ae57-1f0dc5c9c44d' User entered '23 Jan 2021 08:04:04'	System	23 Jan 2021 13:04:08
	System	23 Jan 2021 13:04:08

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-01T12:00:43', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '081fc2a2-a6c7-4493-b0c6-0d0ebc6e3389' User entered 'No (N)'	System	01 Feb 2021 17:05:02

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-01T12:00:59', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '081fc2a2-a6c7-4493-b0c6-0d0ebc6e3389'	System	01 Feb 2021 17:05:02
User entered 'No (N)'	System	01 Feb 2021 17:05:02

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-01T12:01:23', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '081fc2a2-a6c7-4493-b0c6-0d0ebc6e3389' User entered '01 Feb 2021 12:01:23'	System	01 Feb 2021 17:05:02
	System	01 Feb 2021 17:05:02

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-13T08:06:30', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '160fc87e-3cbd-480a-8ca3-41eb2d250f9e'	System	13 Feb 2021 13:06:55
User entered 'No (N)'	System	13 Feb 2021 13:06:55

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-13T08:06:34', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '160fc87e-3cbd-480a-8ca3-41eb2d250f9e'	System	13 Feb 2021 13:06:55
User entered 'No (N)'	System	13 Feb 2021 13:06:55

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-13T08:06:52', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '160fc87e-3cbd-480a-8ca3-41eb2d250f9e'	System	13 Feb 2021 13:06:55
User entered '13 Feb 2021 08:06:52'	System	13 Feb 2021 13:06:55

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-22T12:05:13', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '82499d5b-81b7-4246-8e6d-237fc38cbcfdf' User entered 'No (N)'	System	22 Feb 2021 17:11:18

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-22T12:05:27', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '82499d5b-81b7-4246-8e6d-237fc38cbcf' User entered 'No (N)'	System	22 Feb 2021 17:11:18
	System	22 Feb 2021 17:11:18

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-02-22T12:05:32', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '82499d5b-81b7-4246-8e6d-237fc38cbcfdf' User entered '22 Feb 2021 12:05:32'	System	22 Feb 2021 17:11:18
	System	22 Feb 2021 17:11:18

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-01T14:27:31-05:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e4ad1c51-8e98-4f72-bbee-25f6a0fcdd6a' User entered 'No (N)'	System	01 Mar 2021 19:28:01

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-01T14:27:50-05:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e4ad1c51-8e98-4f72-bbee-25f6a0fcdd6a' User entered 'No (N)'	System	01 Mar 2021 19:28:01

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-01T14:27:59-05:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'e4ad1c51-8e98-4f72-bbee-25f6a0fcdd6a' User entered '01 Mar 2021 14:27:59'	System	01 Mar 2021 19:28:01
	System	01 Mar 2021 19:28:01

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-07T09:10:10-05:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '772b84a0-a6db-4dbb-b244-04e0ca71e0ec'	System	07 Mar 2021 14:10:32
User entered 'No (N)'	System	07 Mar 2021 14:10:32

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-07T09:10:19-05:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '772b84a0-a6db-4dbb-b244-04e0ca71e0ec'	System	07 Mar 2021 14:10:32
User entered 'No (N)'	System	07 Mar 2021 14:10:32

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-07T09:10:30-05:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '772b84a0-a6db-4dbb-b244-04e0ca71e0ec' User entered '07 Mar 2021 09:10:30'	System	07 Mar 2021 14:10:32
	System	07 Mar 2021 14:10:32

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-16T18:31:24-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c51f101d-a66e-43c9-8345-b0f3398992c0'	System	16 Mar 2021 22:31:40
User entered 'No (N)'	System	16 Mar 2021 22:31:40

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-16T18:31:31-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c51f101d-a66e-43c9-8345-b0f3398992c0'	System	16 Mar 2021 22:31:40
User entered 'No (N)'	System	16 Mar 2021 22:31:40

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-16T18:31:38-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'c51f101d-a66e-43c9-8345-b0f3398992c0' User entered '16 Mar 2021 18:31:38'	System	16 Mar 2021 22:31:40
	System	16 Mar 2021 22:31:40

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-23T18:21:21-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd15ff8c7-43ac-4cc5-a233-22197608cd4f' User entered 'No (N)'	System	23 Mar 2021 22:21:39

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-23T18:21:26-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd15ff8c7-43ac-4cc5-a233-22197608cd4f' User entered 'No (N)'	System	23 Mar 2021 22:21:39

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-23T18:21:36-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'd15ff8c7-43ac-4cc5-a233-22197608cd4f' User entered '23 Mar 2021 18:21:36'	System	23 Mar 2021 22:21:39

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-31T08:41:47-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1db29592-82dc-4df8-b095-c3aaed2f47f2'	System	31 Mar 2021 12:44:54
User entered 'No (N)'	System	31 Mar 2021 12:44:54

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-31T08:41:52-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1db29592-82dc-4df8-b095-c3aaed2f47f2'	System	31 Mar 2021 12:44:54
User entered 'No (N)'	System	31 Mar 2021 12:44:54

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-31T08:42:00-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '1db29592-82dc-4df8-b095-c3aaed2f47f2'	System	31 Mar 2021 12:44:54
User entered '31 Mar 2021 08:42:00'	System	31 Mar 2021 12:44:54

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-06T12:27:11-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'bd746a43-e53f-4075-8021-3a7407934249'	System	06 Apr 2021 16:37:46
User entered 'No (N)'	System	06 Apr 2021 16:37:46

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-06T12:37:32-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'bd746a43-e53f-4075-8021-3a7407934249'	System	06 Apr 2021 16:37:46
User entered 'No (N)'	System	06 Apr 2021 16:37:46

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-06T12:37:43-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'bd746a43-e53f-4075-8021-3a7407934249'	System	06 Apr 2021 16:37:46
User entered '06 Apr 2021 12:37:43'	System	06 Apr 2021 16:37:46

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-12T12:48:38-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0cf95e36-a256-4812-8cdb-7d77c186e999'	System	12 Apr 2021 16:48:53
User entered 'No (N)'	System	12 Apr 2021 16:48:53

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-12T12:48:42-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0cf95e36-a256-4812-8cdb-7d77c186e999'	System	12 Apr 2021 16:48:53
User entered 'No (N)'	System	12 Apr 2021 16:48:53

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-12T12:48:47-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '0cf95e36-a256-4812-8cdb-7d77c186e999'	System	12 Apr 2021 16:48:53
User entered '12 Apr 2021 12:48:47'	System	12 Apr 2021 16:48:53

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-17T16:33:21-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '269251f9-ed07-45d6-ae7d-3021a225fc16'	System	17 Apr 2021 20:33:48
User entered 'No (N)'	System	17 Apr 2021 20:33:48

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-17T16:33:27-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '269251f9-ed07-45d6-ae7d-3021a225fc16'	System	17 Apr 2021 20:33:48
User entered 'No (N)'	System	17 Apr 2021 20:33:48

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-17T16:33:42-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '269251f9-ed07-45d6-ae7d-3021a225fc16'	System	17 Apr 2021 20:33:48
User entered '17 Apr 2021 16:33:42'	System	17 Apr 2021 20:33:48

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-26T12:41:15-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b811ac6e-0766-4a70-9019-407226ae90a3'	System	26 Apr 2021 16:41:26
User entered 'No (N)'	System	26 Apr 2021 16:41:26

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

Have you been exposed to someone with 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 (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-26T12:41:19-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b811ac6e-0766-4a70-9019-407226ae90a3'	System	26 Apr 2021 16:41:26
User entered 'No (N)'	System	26 Apr 2021 16:41:26

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-04-26T12:41:24-04:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: 'b811ac6e-0766-4a70-9019-407226ae90a3' User entered '26 Apr 2021 12:41:24'	System	26 Apr 2021 16:41:26
	System	26 Apr 2021 16:41:26

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:09:47

US3532231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:05:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:09:47
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:09:47

US3532231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:05:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:13:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-01T14:28:07-05:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '26987968-4cbd-42c1-a09e-4f692e5c5be7'	System	01 Mar 2021 19:28:16
User entered 'No (N)'	System	01 Mar 2021 19:28:16

US3532231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:05:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:13:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0566ED0B-BE4D-4002-BD68-3B35EFD080B5)', Time: '2021-03-01T14:28:14-05:00', User OID: 'PatientReportedOutcome (US3532231)', ODM File OID: '26987968-4cbd-42c1-a09e-4f692e5c5be7' User entered '01 Mar 2021 14:28:14'	System	01 Mar 2021 19:28:16
	System	01 Mar 2021 19:28:16

US3532231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:43:39
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:03

US3532231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:43:39
User entered '23 Nov 2020'	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:03

US3532231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:43:39
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:03

US3532231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:43:39
User entered empty.	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:03

US3532231

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:43:39
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:09

US3532231

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:46:42
User entered 'I'	System	29 Dec 2020 21:04:09

US3532231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:22

US3532231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '29 Dec 2020'	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:22

US3532231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:22

US3532231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:22

US3532231

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Dec 2020 21:04:27

US3532231

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered 'I'	System	29 Dec 2020 21:04:27

US3532231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 14:34:53

US3532231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 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)	03 Feb 2021 07:46:41
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Had to leave message. Subject did not return call until today.' (Site from System).	Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 14:35:14
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	02 Feb 2021 14:34:53
User entered '2 Feb 2021'	Cindy Lubbers (b) (4) (b) (4)	02 Feb 2021 14:34:53

US3532231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	02 Feb 2021 14:34:53

US3532231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	02 Feb 2021 14:34:53

US3532231

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	02 Feb 2021 14:35:22

US3532231

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered 'I'	System	02 Feb 2021 14:35:22

US3532231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	26 Feb 2021 18:55:01

US3532231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '26 Feb 2021'	Cindy Lubbers (b) (4)	26 Feb 2021 18:55:01

US3532231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Contact Made (CONTACT MADE)'	Cindy Lubbers (b) (4)	26 Feb 2021 18:55:01

US3532231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	26 Feb 2021 18:55:01

US3532231

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	26 Feb 2021 18:55:05

US3532231

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered 'I'	System	26 Feb 2021 18:55:05

US3532231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	22 Mar 2021 21:06:57

US3532231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '22 Mar 2021'	(b) (4) Cindy Lubbers (b) (4)	22 Mar 2021 21:06:57

US3532231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Clinic (Clinic)'	Cindy Lubbers (b) (4)	22 Mar 2021 21:06:57

US3532231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered 'VISIT4'	System	22 Mar 2021 21:06:57

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered empty.	System	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered empty.	System	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered empty.	System	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered empty.	System	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered empty.	System	01 Apr 2021 18:58:32

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50

US3532231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50

US3532231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Cindy Lubbers (b) (4)	22 Mar 2021 21:07:10

US3532231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	22 Mar 2021 21:07:10

US3532231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	22 Mar 2021 21:07:46

US3532231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '22 Mar 2021'	Cindy Lubbers (b) (4)	22 Mar 2021 21:07:46

US3532231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '10:30'	Cindy Lubbers (b) (4)	22 Mar 2021 21:07:46

US3532231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered '22 Mar 2021 10:30'	System	22 Mar 2021 21:07:46

US3532231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	22 Mar 2021 21:07:51

US3532231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:31:50
User entered 'I'	System	22 Mar 2021 21:07:51

US3532231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	28 Apr 2021 22:00:37
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	28 Apr 2021 17:41:20
	(b) (4)	

US3532231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	28 Apr 2021 22:00:37
	(b) (4)	
User entered '28 Apr 2021'	Cindy Lubbers (b) (4)	28 Apr 2021 17:41:20
	(b) (4)	

US3532231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	28 Apr 2021 22:00:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	28 Apr 2021 17:41:20

US3532231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:05:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	28 Apr 2021 22:00:37
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	28 Apr 2021 17:41:20

US3532231

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	28 Apr 2021 22:00:37
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	28 Apr 2021 17:41:24
	(b) (4)	

US3532231

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:05:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 17:41:24

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:45
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '5 Nov 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:13:25

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:45
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '09:30'	Laila Hussaini (b) (4)	05 Nov 2020 18:13:25

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:45
User entered '5 Nov 2020 09:30'	System	05 Nov 2020 18:13:25

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:45
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:13:25

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:45
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	05 Nov 2020 18:13:25

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 1 (Day 1)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '29 Oct 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 2 (Day 2)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '30 Oct 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:20

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 3 (Day 3)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '31 Oct 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	05 Nov 2020 18:14:35

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:35

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 4 (Day 4)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '1 Nov 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	05 Nov 2020 18:15:07
User entered 'Mild (Mild)'	(b) (4)	
	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57
	(b) (4)	

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:14:57

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 5 (Day 5)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '2 Nov 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:15:36

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 6 (Day 6)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '3 Nov 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:15:53

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 7 (Day 7)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '4 Nov 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:14

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 8 (Day 8)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '5 Nov 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '97'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '97.6' F	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

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Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:48

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 9 (Day 9)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '6 Nov 2020'	(b) (4) Laila Hussaini (b) (4) (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '98'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '97.1' F	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Moderate (Moderate)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	06 Nov 2020 17:02:02

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 10 (Day 10)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '7 Nov 2020'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '97'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '97.9' F	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	07 Nov 2020 15:12:46

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 11 (Day 11)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '08 Nov 2020'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Not Done (Not Done)'	Laila Hussaini (b) (4)	09 Nov 2020 18:55:29

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 12 (Day 12)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '09 Nov 2020'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '98'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User entered '%'	System	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '98.2' F	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	09 Nov 2020 18:59:56

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '5 Nov 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 13:48:28
User entered 'No (N)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	10 Nov 2020 13:48:28
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:48:05
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4)	06 Nov 2020 14:48:05
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 14:47:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 14:47:46
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	06 Nov 2020 14:47:46
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:16:58
User entered empty.	Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '5 Nov 2020'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	05 Nov 2020 18:16:58

US3532231

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:18:01
User entered '0'	System	06 Nov 2020 14:47:46

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per your response since the sample was collected then please update the data under Saliva collection form of illness visit' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 07:56:27
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per your response since the sample was collected then please update the data under Saliva collection form of illness visit' answered with 'ADDED' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:44:19
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per your response since the sample was collected then please update the data under Saliva collection form of illness visit' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:46:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:46:49
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Subject collected sample a day earlier than needed. Is the D3 saliva sample. Subject was COVID - so no EDC entry for saliva.' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	08 Nov 2020 18:05:29
User entered '08 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	06 Nov 2020 21:44:06

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Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:41:40
User entered '8 Oct 2020'	Laila Hussaini (b) (4)	08 Oct 2020 22:54:16

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Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '18:00'	Laila Hussaini (b) (4)	08 Oct 2020 22:54:16

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Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:19
User entered '08 Oct 2020 18:00'	System	06 Nov 2020 21:44:06
User entered '8 Oct 2020 18:00'	System	08 Oct 2020 22:54:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:54:16

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Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:05:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	08 Oct 2020 22:54:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Day 1 (Day 1)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '8 Oct 2020'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '95'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User entered '%'	System	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '99.6' F	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Moderate (Moderate)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'None (None)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:05:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:16

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '8 Oct 2020'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:30

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Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	27 Oct 2020 16:38:56
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	27 Oct 2020 14:36:42
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:30

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 14:37:07
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	27 Oct 2020 14:37:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	27 Oct 2020 14:36:42
User closed query 'Data is required. Please complete.' (Site from System).	Cindy Lubbers (b) (4)	27 Oct 2020 14:36:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	27 Oct 2020 14:32:00
User opened query 'Data is required. Please complete.' (Site from System).	Laila Hussaini (b) (4)	27 Oct 2020 14:32:00
User entered empty.	(b) (4)	
	System	08 Oct 2020 22:55:30
	Laila Hussaini (b) (4)	08 Oct 2020 22:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '8 Oct 2020'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:30

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:30

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Laila Hussaini (b) (4)	08 Oct 2020 22:55:30

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Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Laila Hussaini (b) (4)	08 Oct 2020 22:55:30

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	08 Oct 2020 22:55:30

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Laila Hussaini (b) (4)	08 Oct 2020 22:55:30

US3532231

Folder: Covid-19 Assessment 08 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:05:38

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:31
User entered '0'	System	27 Oct 2020 14:32:00

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Folder: Covid-19 Assessment 08 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:05:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:17:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 14:54:47
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	06 Nov 2020 14:54:47
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	27 Oct 2020 14:38:50
	Cindy Lubbers (b) (4)	27 Oct 2020 14:38:50
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:05:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

US3532231

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:05:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Nov 2020 15:47:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Per response "sample listed in EDC under saliva collection form day 5", however the day 5 date is 09NOV2020 and the date in query is regarding 09OCT2020, please verify and update accordingly.Thanks' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 06:55:43
Query 'Per GCL Lab Reconciliation: Saliva: Per response "sample listed in EDC under saliva collection form day 5", however the day 5 date is 09NOV2020 and the date in query is regarding 09OCT2020, please verify and update accordingly.Thanks' answered with 'sample collected on both Day 3 and Day 5' (Site from DM).	Laila Hussaini (b) (4)	09 Apr 2021 21:01:32
User opened query 'Per GCL Lab Reconciliation: Saliva: Per response "sample listed in EDC under saliva collection form day 5", however the day 5 date is 09NOV2020 and the date in query is regarding 09OCT2020, please verify and update accordingly.Thanks' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:07:08
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:07:08
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'sample listed in EDC under saliva collection form day 5' (Site from DM).	Laila Hussaini (b) (4)	06 Apr 2021 13:01:05
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:41:55
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '07 Nov 2020'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:05:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:05:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Nov 2020 15:47:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the date has been updated as per response.Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:10:21
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the date has been updated as per response.Thanks' answered with 'updated' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 17:40:02
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the date has been updated as per response.Thanks' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:11:49
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 09:11:49
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'should be Nov. Will update in PPD' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	18 Jan 2021 15:29:31
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:59:35
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:44:59

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EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated PPD' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	14 Nov 2020 18:16:47
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 08:35:10
User entered '09 Nov 2020'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:05:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:05:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

US3532231

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	11 Nov 2020 15:47:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:05:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:05:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

US3532231

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	11 Nov 2020 15:47:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:05:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:05:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

US3532231

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:05:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:05:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

US3532231

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	11 Nov 2020 15:47:15
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:05:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:05:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

US3532231

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Kathy Stephens (b) (4) (b) (4)	11 Nov 2020 15:47:15

US3532231

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Nov 2020 15:45:15

US3532231

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '05 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Kathy Stephens (b) (4)	11 Nov 2020 15:46:25
User entered '08 Oct 2020'	(b) (4)	
	Kathy Stephens (b) (4)	11 Nov 2020 15:45:15
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Clinic (Clinic)'	Kathy Stephens (b) (4)	11 Nov 2020 15:45:15

US3532231

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User entered 'SICKD1'	System	11 Nov 2020 15:45:15

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Nov 2020 15:46:25
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	11 Nov 2020 15:46:25
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Nov 2020 15:46:18
User entered '05 Nov 2020'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '09:44'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User entered '05 Nov 2020 09:44'	System	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Kathy Stephens (b) (4)	11 Nov 2020 15:46:18
DataPoint set to visible.	(b) (4) System	11 Nov 2020 15:45:15

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered missing code ND - Not Done.	(b) (4) Kathy Stephens (b) (4)	11 Nov 2020 15:46:18
DataPoint set to visible.	(b) (4) System	11 Nov 2020 15:45:15

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '97.6' F	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (Oral)'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '57'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User entered 'bpm'	System	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '20'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User entered 'breaths/min'	System	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '119'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User entered 'mmHg'	System	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '84'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User entered 'mmHg'	System	11 Nov 2020 15:46:18

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36

US3532231

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:05:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36

US3532231

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:42

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:05:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '05 Nov 2020'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:42

US3532231

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:05:38

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:50

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Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 08:05:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:25:36
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '05 Nov 2020'	Kathy Stephens (b) (4)	11 Nov 2020 15:46:50

US3532231

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

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:24
	(b) (4)	

US3532231

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

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '12 Jan 2021'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:24
	(b) (4)	

US3532231

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

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[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 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Home (Home)'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:24
	(b) (4)	

US3532231

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

Form: Visit Date

Generated On: 10 Jun 2021 08:05:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 15:12:24

US3532231

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '12 Jan 2021'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:45
	(b) (4)	

US3532231

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[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 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:08:46

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:45
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:08:46

US3532231

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '12 Jan 2021'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:45
	(b) (4)	

US3532231

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:45
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:05:32
User entered 'mRNA-1273 (mRNA-1273)'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:45
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:05:32
User entered 'mRNA-1273 (mRNA-1273)'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:45
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	12 Jan 2021 15:12:45
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User entered empty.	System	12 Jan 2021 15:12:45

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

Form: Unblinding

Generated On: 10 Jun 2021 08:05:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User entered empty.	System	12 Jan 2021 15:12:45

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Jan 2021 15:13:00
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '12 Jan 2021'	Lisa Macoy (b) (4)	12 Jan 2021 15:13:00
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '09:41'	Lisa Macoy (b) (4)	12 Jan 2021 15:13:00
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:05:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User entered '12 Jan 2021 09:41'	System	12 Jan 2021 15:13:00

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:05:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Jan 2021 15:13:14
	(b) (4)	

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:05:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '12 Jan 2021'	Lisa Macoy (b) (4)	12 Jan 2021 15:13:14
	(b) (4)	

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:05:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '09:45' reason for change: Data Entry Error	Lisa Macoy (b) (4)	12 Jan 2021 15:13:23
	(b) (4)	
User entered '09:41'	Lisa Macoy (b) (4)	12 Jan 2021 15:13:14
	(b) (4)	

US3532231

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:05:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:59:52
User entered '12 Jan 2021 09:45'	System	12 Jan 2021 15:13:23
User entered '12 Jan 2021 09:41'	System	12 Jan 2021 15:13:14

US3532231

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:05:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:42:00
User closed query 'Per DM CLR RQ: Response noted, however note that per Diary dose 2, Muscle aches all over was started on 01 OCT 2020 and Chills was started on 05 OCT 2020 and lasted beyond day 7 post injection till 08 OCT 2020. Please reconcile and update start date of recorded AE's accordingly or else clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:26:54
Query 'Per DM CLR RQ: Response noted, however note that per Diary dose 2, Muscle aches all over was started on 01 OCT 2020 and Chills was started on 05 OCT 2020 and lasted beyond day 7 post injection till 08 OCT 2020. Please reconcile and update start date of recorded AE's accordingly or else clarify. ' answered with 'updated all 3 start dates' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	21 Apr 2021 14:47:42
User opened query 'Per DM CLR RQ: Response noted, however note that per Diary dose 2, Muscle aches all over was started on 01 OCT 2020 and Chills was started on 05 OCT 2020 and lasted beyond day 7 post injection till 08 OCT 2020. Please reconcile and update start date of recorded AE's accordingly or else clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 09:29:25
User closed query 'Per protocol any Solicited local or systemic AR's lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as AE's in the participant's Adverse Event eCRF. Per subject's diary, "Chills" , and "Muscle aches all over" lasted beyond day 7 post injection. Please reconcile and enter events as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 09:29:25

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:05:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per protocol any Solicited local or systemic AR's lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as AE's in the participant's Adverse Event eCRF. Per subject's diary, "Chills" , and "Muscle aches all over" lasted beyond day 7 post injection. Please reconcile and enter events as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'Added to AEs' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	19 Apr 2021 20:17:50
User opened query 'Per protocol any Solicited local or systemic AR's lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as AE's in the participant's Adverse Event eCRF. Per subject's diary, "Chills" , and "Muscle aches all over" lasted beyond day 7 post injection. Please reconcile and enter events as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 17:45:37
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:30:18
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	01 Oct 2020 15:27:26

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
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)	03 Dec 2020 03:23:08
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 'do not meet covid illness visit criteria' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	01 Dec 2020 18:42:23
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)	01 Dec 2020 09:19:25
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:00:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:00:44
Data point term sent to Coder	System	27 Oct 2020 15:59:16
DataPoint Un-verified.	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 15:58:33
Coding entries removed.	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 15:58:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'FATigUE' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	27 Oct 2020 15:58:33
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)	20 Oct 2020 05:49:53
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 'PI determined no visit needed. Subject had no other symptoms and stated he had worked "very hard" out in the yard that day.' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	19 Oct 2020 14:06:24
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)	19 Oct 2020 10:29:13
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:34
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 00:11:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 00:11:58
Data point term sent to Coder	System	01 Oct 2020 15:30:29
User entered 'Fatigue'	Cindy Lubbers (b) (4) (b) (4)	01 Oct 2020 15:29:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:41
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:36
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:43
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:45
User entered '17 Sep 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:47
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User entered empty.	System	01 Oct 2020 15:29:39

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:50
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:53
User entered '19 Sep 2020'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:55
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User entered empty.	System	01 Oct 2020 15:29:39

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:10:57
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:00
User entered 'No (N)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:04
User entered '0'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:10
User entered '0'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:06
User entered '0'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:13
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:15
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:16
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:19
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:22
User entered '0'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:26
User entered '0'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:28
User entered '0'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
DataPoint Un-verified.	Cindy Lubbers (b) (4)	20 Apr 2021 13:06:23
	(b) (4)	
Signature has been broken.	Cindy Lubbers (b) (4)	20 Apr 2021 13:06:23
	(b) (4)	
User entered 'Related (RELATED)' reason for change: New Information	Cindy Lubbers (b) (4)	20 Apr 2021 13:06:23
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:30
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:32
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
DataPoint Un-verified.	Cindy Lubbers (b) (4)	20 Apr 2021 13:06:23
	(b) (4)	
Signature has been broken.	Cindy Lubbers (b) (4)	20 Apr 2021 13:06:23
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cindy Lubbers (b) (4)	20 Apr 2021 13:06:23
reason for change: New Information	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:34
	(b) (4)	
User entered 'None (NONE)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:37
User entered 'I'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:39
User entered '0'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:41
User entered '0'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:48
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:11:49
User entered empty.	Cindy Lubbers (b) (4)	01 Oct 2020 15:29:39
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User entered '0'	System	01 Oct 2020 15:29:39

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11
User entered '0'	System	01 Oct 2020 15:29:39

US3532231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:11

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:54:43
User entered	System	12 Oct 2020 15:54:38
'USA-US077-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	12 Oct 2020 15:54:38

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User closed query 'PV Query: Please consider updating the event term to the more specific community acquired pneumonia.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:54:47
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Community acquired pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:38:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:38:42
Data point term sent to Coder	System	10 Nov 2020 14:37:11
Query 'PV Query: Please consider updating the event term to the more specific community acquired pneumonia.' answered with 'done' (Site from Safety).	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 14:36:21
DataPoint Un-verified.	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 14:36:14
Coding entries removed.	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 14:36:14
User entered 'Community acquired PNEUMONIA' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 14:36:14
User opened query 'PV Query: Please consider updating the event term to the more specific community acquired pneumonia.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:12:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 14:27:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 14:27:27
Data point term sent to Coder	System	11 Oct 2020 14:26:15
User entered 'Pneumonia'	Cindy Lubbers (b) (4) (b) (4)	11 Oct 2020 14:25:55

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'No (N)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	11 Oct 2020 14:25:55

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '10 Oct 2020'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered empty.	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 14:25:55

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Oct 2020 14:04:22
DataPoint Un-verified.	Cindy Lubbers (b) (4)	14 Oct 2020 19:14:47
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	19 Oct 2020 14:04:22
DataPoint Un-verified.	Cindy Lubbers (b) (4)	19 Oct 2020 14:04:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:49
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered empty.	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:14:52
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'Grade 4 (Grade 4)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '0'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '0'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:14:00
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 06:39:26
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'subject has not been discharged yet. Not in ICU' (Site from System).	Cindy Lubbers (b) (4) (b) (4)	11 Oct 2020 14:28:18
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Oct 2020 14:25:55
User entered 'I'	Cindy Lubbers (b) (4) (b) (4)	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '10 Oct 2020'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Un-verified.	Cindy Lubbers (b) (4)	19 Oct 2020 14:04:22
User entered '16 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Oct 2020 14:04:22
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered empty.	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'No (N)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered empty.	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '0'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '0'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '0'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User closed query 'PV Query: As subject had already received both doses of study drug, please update action taken to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:39
Query 'PV Query: As subject had already received both doses of study drug, please update action taken to not applicable.' answered with 'done' (Site from Safety).	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 14:41:19
DataPoint Un-verified.	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 14:41:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 14:41:12
User opened query 'PV Query: As subject had already received both doses of study drug, please update action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 11:55:54
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'None (NONE)'	Cindy Lubbers (b) (4) (b) (4)	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '0'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'I'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered '0'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Un-verified.	(b) (4)	
	Cindy Lubbers (b) (4)	19 Oct 2020 14:04:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Cindy Lubbers (b) (4)	19 Oct 2020 14:04:22
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered empty.	Cindy Lubbers (b) (4)	11 Oct 2020 14:25:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:11
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User closed query 'Per DM CLR: SAE Narrative = ULTRA SOUND OF THE ABDOMEN . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 06:57:22
User closed query 'Per DM CLR: SAE Narrative = CHEST X-RAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 06:57:20
Query 'Per DM CLR: SAE Narrative = ULTRA SOUND OF THE ABDOMEN . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Noted' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:17:27
Query 'Per DM CLR: SAE Narrative = CHEST X-RAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Noted' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:17:22
User opened query 'Per DM CLR: SAE Narrative = ULTRA SOUND OF THE ABDOMEN . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:03:55
User opened query 'Per DM CLR: SAE Narrative = CHEST X-RAY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:03:50
User closed query 'PV Query: Please confirm if any additional liver diagnostics have been performed. If so, please provide results.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:52:23
User closed query 'PV Query: Please confirm if the subject has newly diagnosed liver disease (from imaging). If so, this should be reported as separate AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:52:19

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if any additional liver diagnostics have been performed. If so, please provide results.' answered with 'No additional test done at this time' (Site from Safety).	Cindy Lubbers (b) (4) (b) (4)	24 Nov 2020 20:51:09
Query 'PV Query: Please confirm if the subject has newly diagnosed liver disease (from imaging). If so, this should be reported as separate AE/SAE.' answered with 'New AE #' (Site from Safety).	Cindy Lubbers (b) (4) (b) (4)	24 Nov 2020 20:50:53
User opened query 'PV Query: Please confirm if any additional liver diagnostics have been performed. If so, please provide results.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 18:44:40
User opened query 'PV Query: Please confirm if the subject has newly diagnosed liver disease (from imaging). If so, this should be reported as separate AE/SAE.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 18:44:33
User closed query 'PV Query: Please confirm if any of the discharge diagnoses (transaminitis, hepatic steatosis, toxic encephalopathy, B12 deficiency, macrocytic anemia, diarrhea) met SAE criteria. If so, please add to the EDC.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	11 Nov 2020 16:55:11
Query 'PV Query: Please confirm if any of the discharge diagnoses (transaminitis, hepatic steatosis, toxic encephalopathy, B12 deficiency, macrocytic anemia, diarrhea) met SAE criteria. If so, please add to the EDC.' answered with 'toxic encephalopathy added to chart' (Site from Safety).	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 19:51:21
User opened query 'PV Query: Please confirm if any of the discharge diagnoses (transaminitis, hepatic steatosis, toxic encephalopathy, B12 deficiency, macrocytic anemia, diarrhea) met SAE criteria. If so, please add to the EDC.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	06 Nov 2020 16:12:12
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) (b) (4)	28 Oct 2020 16:02:13

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:02:00
User closed query 'PV Query: Please provide the subject's initial oxygen saturation level. Did the subject require supplemental oxygen?' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:01:30
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)	28 Oct 2020 16:01:15
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 16:00:25
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records sent' (Site from Safety).	Cindy Lubbers (b) (4)	27 Oct 2020 20:42:36
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'records in chart' (Site from Safety).	Cindy Lubbers (b) (4)	27 Oct 2020 17:58:16
Query 'PV Query: Please provide the subject's initial oxygen saturation level. Did the subject require supplemental oxygen?' answered with 'done' (Site from Safety).	Cindy Lubbers (b) (4)	27 Oct 2020 15:38:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT TAKEN TO ED WITH FEVER, CONFUSION, DARK URINE . ADMITTED FOR PNEUMONIA.- WAS TESTED FOR COVID- NEGATIVE RESULT. CHEST X-RAY REVEALED DENSE RIGHT POSTERIOR PERIHILAR CONSOLIDATION WITH AIR BRONCHOGRAMS SUGGESTIVE OF PNEUMONIA.O2 SAT 95% ON ROOM AIR. started on R0cephen and azithromax.Ceftriaxone and cefdinir discontinued due to elevated liver enzymes.Ultra sound of the abdomen revealed hepatic steatosis and/or chronic liver disease' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	27 Oct 2020 15:38:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'done' (Site from Safety).	Cindy Lubbers (b) (4)	27 Oct 2020 15:29:18
User entered 'SUBJECT TAKEN TO ED WITH FEVER, CONFUSION, DARK URINE . ADMITTED FOR PNEUMONIA. RECEIVING ROCEPHIN AND ZITHROMAX. SUBJECT WAS TESTED FOR COVID- NEGATIVE RESULT. Chest x-ray revealed dense right posterior perihilar consolidation with air bronchograms suggestive of pneumonia.O2 sat 95% on room air.' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	27 Oct 2020 15:28:58
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with (b) (6) ' (Site from Safety).	Cindy Lubbers (b) (4)	27 Oct 2020 15:15:04
DataPoint Un-verified.	Cindy Lubbers (b) (4)	27 Oct 2020 15:14:57
User entered 'SUBJECT TAKEN TO ED WITH FEVER, CONFUSION, DARK URINE . ADMITTED FOR PNEUMONIA. RECEIVING ROCEPHIN AND ZITHROMAX. Subject was tested for COVID- negative result.' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	27 Oct 2020 15:14:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 11:56:18
User opened query 'PV Query: Please provide the subject's initial oxygen saturation level. Did the subject require supplemental oxygen?' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 11:56:08
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 11:55:43
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)	20 Oct 2020 11:55:25
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 11:54:43
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 19:14:38
User entered 'Subject taken to ED with fever, confusion, dark urine . Admitted for pneumonia. Receiving Rocephin and Zithromax.'	Cindy Lubbers (b) (4) (b) (4)	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Oct 2020 14:25:55

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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)
User entered '1'	System	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Oct 2020 14:25:55

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:27:26
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:14:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 12:59:04
Un-reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 12:49:56
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 12:49:56
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 12:49:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 12:49:56
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 16:56:26
User entered 'USA-US077-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	11 Nov 2020 16:56:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLG: Encephalopathies, HLT: Encephalopathies toxic and metabolic, PT: Toxic encephalopathy, LLT: Toxic encephalopathy - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 19:51:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 19:51:40
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 19:50:42
User entered 'toxic encephalopathy'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '10 Oct 2020'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
User entered empty.	System	10 Nov 2020 19:50:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '16 Oct 2020'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
User entered empty.	System	10 Nov 2020 19:50:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:27:26
User closed query 'Thank you for stating that this AE was not reason subject admitted to hospital. Please confirm if this AE required Prolongs hospitalization or otherwise fulfills SAE criteria? If Not, it should not be reported as SAE.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 14:14:33
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:14:30
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	06 Apr 2021 13:07:48
User closed query 'PV Urgent Query: "Is the adverse event serious" was marked as No; however, seriousness criteria is provided. Please review and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 12:49:44
Query 'PV Urgent Query: "Is the adverse event serious" was marked as No; however, seriousness criteria is provided. Please review and update accordingly.' answered with 'Ae did not prolong hospitalization or meet SAE criteria ' (Site from Safety).	Cindy Lubbers (b) (4)	05 Apr 2021 21:25:57
Query 'Thank you for stating that this AE was not reason subject admitted to hospital. Please confirm if this AE required Prolongs hospitalization or otherwise fulfills SAE criteria? If Not, it should not be reported as SAE.' answered with 'Did not prolong hospital stay and did not meet SAE criteria' (Site from CRA).	Cindy Lubbers (b) (4)	05 Apr 2021 21:25:16
User opened query 'PV Urgent Query: "Is the adverse event serious" was marked as No; however, seriousness criteria is provided. Please review and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:47:20
User opened query 'Thank you for stating that this AE was not reason subject admitted to hospital. Please confirm if this AE required Prolongs hospitalization or otherwise fulfills SAE criteria? If Not, it should not be reported as SAE.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:50:10

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Please check with source notes if this AE Prolongs hospitalization or otherwise fulfills SAE criteria? If Not, it should be reported only as AE, not SAE.' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:50:10
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 04:57:28
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	30 Mar 2021 22:10:08
User entered 'No (N)' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	30 Mar 2021 22:10:08
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	30 Mar 2021 22:09:40
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	30 Mar 2021 22:09:40
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Per monitor request, PI reviewed. Not SAE because it was not reason subject admitted to hospital ,resolved with treatment given for CAP' (Site from System).	Cindy Lubbers (b) (4)	30 Mar 2021 22:09:02
Query 'Please check with source notes if this AE Prolongs hospitalization or otherwise fulfills SAE criteria? If Not, it should be reported only as AE, not SAE.' answered with 'Per monitor request, PI reviewed. Not SAE because it was not reason subject admitted to hospital ,resolved with treatment given for CAP' (Site from CRA).	Cindy Lubbers (b) (4)	30 Mar 2021 22:08:58
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	30 Mar 2021 22:06:05
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	30 Mar 2021 22:06:05
DataPoint Un-verified.	Cindy Lubbers (b) (4)	30 Mar 2021 22:06:05
Signature has been broken.	Cindy Lubbers (b) (4)	30 Mar 2021 22:06:05
User entered 'No (N)' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	30 Mar 2021 22:06:05

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User opened query 'Please check with source notes if this AE Prolongs hospitalization or otherwise fulfills SAE criteria? If Not, it should be reported only as AE, not SAE.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:46:57
	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:27:26
	(b) (4)	
User closed query 'Per CDM: As per data entry event is not serious. Please consider removing hospital admission date, discharge date and admitted to ICU data as this is only needed if requires inpatient or prolongation of existing hospitalization is selected. Review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:21:40
Query 'Per CDM: As per data entry event is not serious. Please consider removing hospital admission date, discharge date and admitted to ICU data as this is only needed if requires inpatient or prolongation of existing hospitalization is selected. Review and update accordingly.' answered with 'completed' (Site from DM).	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 14:14:38
User opened query 'Per CDM: As per data entry event is not serious. Please consider removing hospital admission date, discharge date and admitted to ICU data as this is only needed if requires inpatient or prolongation of existing hospitalization is selected. Review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 03:07:27
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 03:03:47
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'This AE did not prolong the already existing hospitalization for PNA but did occur at the same time therefore hospital data provided.' (Site from System).	Laila Hussaini (b) (4)	06 Apr 2021 13:09:51
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	06 Apr 2021 13:07:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Laila Hussaini (b) (4)	06 Apr 2021 13:07:48
	(b) (4)	
Signature has been broken.	Laila Hussaini (b) (4)	06 Apr 2021 13:07:48
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Laila Hussaini (b) (4)	06 Apr 2021 13:07:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '1'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:27:26
	(b) (4)	
DataPoint Un-verified.	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
Signature has been broken.	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '10 Oct 2020'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:27:26
	(b) (4)	
DataPoint Un-verified.	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
Signature has been broken.	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '16 Oct 2020'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:27:26
	(b) (4)	
DataPoint Un-verified.	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
Signature has been broken.	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Cindy Lubbers (b) (4)	07 Apr 2021 17:01:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User entered 'Not Applicable (NOT APPLICABLE)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 05:54:23
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Resolved with CAP treatment' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:26:00
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:04:17
User entered 'I'	Cindy Lubbers (b) (4) (b) (4)	10 Nov 2020 19:50:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:27:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:14:46
DataPoint Un-verified.	Cindy Lubbers (b) (4)	30 Mar 2021 22:06:05
Signature has been broken.	(b) (4) Cindy Lubbers (b) (4)	30 Mar 2021 22:06:05
User entered 'NOT RELATED TO VACCINE-RELATED TO PNEUMONIA (LISTED IN SAE DATED 10OCT2020) RESOLVED WITH TREATMENT OF CAP-.not an SAE but an AE per criteria' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	30 Mar 2021 22:06:05
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:50:16
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User entered 'NOT RELATED TO VACCINE-RELATED TO PNEUMONIA (LISTED IN SAE DATED 10OCT2020) Resolved with treatment of CAP' reason for change: Data Entry Error	(b) (4) Cindy Lubbers (b) (4)	10 Nov 2020 19:54:12
User entered 'Not related to vaccine- related to pneumonia (listed in SAE dated 10OCT2020)'	Cindy Lubbers (b) (4)	10 Nov 2020 19:50:10
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
User entered '0'	System	30 Mar 2021 22:10:08
User entered '1'	System	30 Mar 2021 22:09:40
User entered '0'	System	30 Mar 2021 22:06:05
User entered '1'	System	10 Nov 2020 19:50:10

US3532231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
User entered '1'	System	10 Nov 2020 19:50:10

US3532231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:20
User entered '0'	System	10 Nov 2020 19:50:10

US3532231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Hepatic steatosis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:51:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:51:29
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 20:50:18
User entered 'Hepatic Steatosis'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '10 Oct 2020' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	28 Jan 2021 18:05:20
	(b) (4)	
User entered '14 Oct 2020'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User entered empty.	System	24 Nov 2020 20:49:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 08:52:28
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'This was originally in the information for SAE 2. Per query , was requested to add this and another one as separate AEs. ' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	28 Jan 2021 18:15:33
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	28 Jan 2021 18:02:40
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:56:18
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	24 Nov 2020 20:49:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Jan 2021 18:11:50
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Jan 2021 18:11:50
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Jan 2021 18:05:20
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Jan 2021 18:05:20
User entered '16 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	28 Jan 2021 18:05:20
	(b) (4)	
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Jan 2021 18:02:40
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User entered empty.	System	24 Nov 2020 20:49:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'None (NONE)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'I'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	28 Jan 2021 18:11:50
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	24 Nov 2020 20:49:57
	(b) (4)	

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User entered '0'	System	24 Nov 2020 20:49:57

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25
User entered '1'	System	24 Nov 2020 20:49:57

US3532231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:25

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Respiratory disorder, LLT: Respiratory disorder - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 18:34:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 18:34:20
	(b) (4)	
Data point term sent to Coder	System	28 Jan 2021 18:33:35
User entered 'Respiratory illness'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '4 Nov 2020'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User entered empty.	System	28 Jan 2021 18:32:40

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '9 Nov 2020'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User entered empty.	System	28 Jan 2021 18:32:40

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'None (NONE)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'I'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:16:24
	(b) (4)	
User entered 'Subject c/o nasal congestion and sore throat.'	Cindy Lubbers (b) (4)	28 Jan 2021 18:32:40
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User entered '0'	System	28 Jan 2021 18:32:40

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31
User entered '1'	System	28 Jan 2021 18:32:40

US3532231

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:31

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 19:24:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 19:24:36
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 19:23:58
User entered 'Generalized muscle aches'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
	(b) (4)	
Signature has been broken.	Kathy Stephens (b) (4)	21 Apr 2021 14:43:34
	(b) (4)	
User entered '01 Oct 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	21 Apr 2021 14:43:34
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '8 Oct 2020'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Apr 2021 14:45:43
Signature has been broken.	Kathy Stephens (b) (4)	21 Apr 2021 14:45:43
	(b) (4)	
User entered '22:30' reason for change: Data Entry Error	Kathy Stephens (b) (4)	21 Apr 2021 14:45:43
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Apr 2021 14:43:34
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User entered '01 Oct 2020 22:30'	System	21 Apr 2021 14:45:43
User entered empty.	System	19 Apr 2021 19:23:29

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '8 Oct 2020'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Apr 2021 14:45:43
Signature has been broken.	Kathy Stephens (b) (4)	21 Apr 2021 14:45:43
	(b) (4)	
User entered '00:00' reason for change: Data Entry Error	Kathy Stephens (b) (4)	21 Apr 2021 14:45:43
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Apr 2021 14:43:34
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User entered '8 Oct 2020 00:00'	System	21 Apr 2021 14:45:43
User entered empty.	System	19 Apr 2021 19:23:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:25:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 19:25:05
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:25:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:23:29
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Related (RELATED)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	20 Apr 2021 13:08:46
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:25:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 19:25:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:25:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:23:29
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:25:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 19:25:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:25:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:23:29
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'None (NONE)' reason for change: Per Query Resolution	Cindy Lubbers (b) (4)	20 Apr 2021 13:08:46
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:25:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 19:25:05
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:25:05
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:23:29
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:57
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Apr 2021 19:25:05
User entered '1' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:25:05
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Apr 2021 19:23:29
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:57
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:25:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 19:25:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Cindy Lubbers (b) (4)	19 Apr 2021 19:25:05
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:23:29
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Day 8 of eDiary'	Cindy Lubbers (b) (4)	19 Apr 2021 19:23:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User entered '0'	System	19 Apr 2021 19:23:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35
User entered '0'	System	19 Apr 2021 19:23:29

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:35

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 19:28:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 19:28:43
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 19:28:01
User entered 'Chills'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
	(b) (4)	
Signature has been broken.	Kathy Stephens (b) (4)	21 Apr 2021 14:46:10
	(b) (4)	
User entered '05 Oct 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	21 Apr 2021 14:46:10
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:27:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 19:27:30
User entered '8 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:27:14
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User entered empty.	System	19 Apr 2021 19:27:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:27:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 19:27:39
User entered 'No (N)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:27:14
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '8 Oct 2020'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User entered empty.	System	19 Apr 2021 19:27:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cindy Lubbers (b) (4)	19 Apr 2021 20:08:30
reason for change: New Information	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Related (RELATED)' reason for change: New Information	Cindy Lubbers (b) (4)	20 Apr 2021 13:07:32
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'I'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Entered in day 8 eDiary'	Cindy Lubbers (b) (4)	19 Apr 2021 19:27:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User entered '0'	System	19 Apr 2021 19:27:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39
User entered '0'	System	19 Apr 2021 19:27:14

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:39

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 19:33:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 19:33:41
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 19:33:06
User entered 'Fatigue'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
	(b) (4)	
Signature has been broken.	Kathy Stephens (b) (4)	21 Apr 2021 14:47:16
	(b) (4)	
User entered '05 Oct 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	21 Apr 2021 14:47:16
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '8 Oct 2020'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User entered empty.	System	19 Apr 2021 19:32:35

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '8 Oct 2020'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User entered empty.	System	19 Apr 2021 19:32:35

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cindy Lubbers (b) (4)	19 Apr 2021 20:09:02
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cindy Lubbers (b) (4)	19 Apr 2021 20:08:53
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 20:05:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 20:05:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	19 Apr 2021 20:05:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:32:35
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'I'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 20:05:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Apr 2021 20:05:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Cindy Lubbers (b) (4)	19 Apr 2021 20:05:03
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Apr 2021 19:32:35
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:07
	(b) (4)	
User entered 'eDiary entry day 8'	Cindy Lubbers (b) (4)	19 Apr 2021 19:32:35
	(b) (4)	

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User entered '0'	System	19 Apr 2021 19:32:35

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44
User entered '0'	System	19 Apr 2021 19:32:35

US3532231

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:05:38

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:57:44

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:42:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per ETRTR: According to SAE "Pneumonia", medication was given for SAE. Please update ConMeds page with Medication dosed, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 21:05:42
Query 'Per ETRTR: According to SAE "Pneumonia", Cindy Lubbers medication was given for SAE. Please update ConMeds page with Medication dosed, thanks.' answered with 'done' (Site from CRA).	(b) (4) (b) (4)	29 Oct 2020 16:07:37
User opened query 'Per ETRTR: According to SAE "Pneumonia", medication was given for SAE. Please update ConMeds page with Medication dosed, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 00:42:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:37:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUVOXAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Sep 2020 06:49:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:49:29
Data point term sent to Coder	System	03 Sep 2020 19:39:56
User entered 'Fluvoxamine'	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Heart Arrhythmia Depression'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '100'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'un UNK 2010'	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:39:19

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 19:41:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:41:46
Data point term sent to Coder	System	03 Sep 2020 19:40:57
User entered 'Famotidine'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'GERD'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '40'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'un UNK 2013'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:40:08

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 19:42:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:42:48
Data point term sent to Coder	System	03 Sep 2020 19:41:59
User entered 'Atorvastatin'	(b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'High Cholesterol'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '20'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'un UNK 2013'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	29 Oct 2020 13:49:12
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	03 Sep 2020 19:41:09
	(b) (4)	
	(b) (4), (b) (6)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	29 Oct 2020 13:49:12
User entered empty.	Cindy Lubbers (b) (4)	03 Sep 2020 19:41:09
	(b) (4), (b) (6)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User entered '1'	System	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User entered '1'	System	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:19
User entered '804 (804)'	System	03 Sep 2020 19:41:09

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 19:43:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:43:48
Data point term sent to Coder	System	03 Sep 2020 19:43:08
User entered 'Bystolic'	(b) (4), (b) (6) [REDACTED] [REDACTED]	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Heart Arrhythmia'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '5'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:42:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 19:42:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 19:42:31
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:42:16
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:42:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 19:51:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:51:48
Data point term sent to Coder	System	03 Sep 2020 19:50:34
User entered 'Wellbutrin'	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Depression'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '150'	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'un UNK 2019'	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:50:21

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
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.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 19:52:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:52:47
Data point term sent to Coder	System	03 Sep 2020 19:51:40
User entered 'Aspirin'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	27 Oct 2020 15:52:19
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per DM CLR: Indication = HEART HEALTH. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 06:16:46
Query 'Per DM CLR: Indication = HEART HEALTH. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 15:52:25
User opened query 'Per DM CLR: Indication = HEART HEALTH. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:33:13
User entered 'Heart Health'	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '81'	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:51:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 07:04:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 07:04:43
Data point term sent to Coder	System	03 Sep 2020 19:55:52
User entered 'Ibuprofen'	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Muscle Aches and general pain'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '400'	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:55:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
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.	(b) (4) Coder Import (b) (4)	03 Sep 2020 20:11:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:11:53
Data point term sent to Coder	System	03 Sep 2020 20:10:20
User entered 'Acetaminophen'	(b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'muscle aches and general pains'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Please add new line with ACETAMINOPHEN=650 mg (per Discharge summary) ' canceled (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:41:14
User opened query 'Please add new line with ACETAMINOPHEN=650 mg (per Discharge summary) ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:25:39
User closed query 'Please check dose with Discharge summary (=650 mg) and change dose here or add new line with new dose' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:25:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Query 'Please check dose with Discharge summary (=650 mg) and change dose here or add new line with new dose' answered with 'Added new line for AE' (Site from CRA).	Cindy Lubbers (b) (4)	30 Mar 2021 18:32:57
User opened query 'Please check dose with Discharge summary (=650 mg) and change dose here or add new line with new dose' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 16:04:03
User entered '325' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	26 Sep 2020 15:25:44
User entered 'unk'	(b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	26 Sep 2020 15:25:44
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cindy Lubbers (b) (4)	26 Sep 2020 15:25:44
	(b) (4)	
User entered 'unknown'	(b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:10:16

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:10:16

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:05:38
[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Sep 2020 20:11:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Sep 2020 20:11:53
Data point term sent to Coder	System	03 Sep 2020 20:11:21
User entered 'Losartan'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '50'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'un UNK 2013'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 20:11:12

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 20:12:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:12:40
Data point term sent to Coder	System	03 Sep 2020 20:12:22
User entered 'Vitamin D3'	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	27 Oct 2020 15:54:22
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per DM CLR: Indication = GENERAL HEALTH. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 06:19:09
Query 'Per DM CLR: Indication = GENERAL HEALTH. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 15:54:30
User opened query 'Per DM CLR: Indication = GENERAL HEALTH. Please review if this Con Med is taken as prophylaxis. If so, kindly update the response to 'Yes'. Update ConMed eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:02:44
User entered 'General Health'	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per CDM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 06:15:11
Query 'Per CDM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 15:54:49
User entered '5000' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 15:54:22
User opened query 'Per CDM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:03:00
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'IU (IU)' reason for change: Data Entry	Cindy Lubbers (b) (4)	27 Oct 2020 15:54:22
Error	(b) (4)	
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'un UNK 2019'	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:11:56

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Oct 2020 15:58:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:58:20
Data point term sent to Coder	System	27 Oct 2020 15:57:05
User entered 'Flonase'	Cindy Lubbers (b) (4) (b) (4)	27 Oct 2020 15:57:03

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'seasonal allergies'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '50'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'ug (ug)'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'once daily (QD)'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Nasal (NASAL)'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '25 Sep 2020'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	27 Oct 2020 15:57:03
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:57:03

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:57:03

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 15:57:03

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:26:47
Data point term sent to Coder	System	29 Oct 2020 15:48:45
Data point term sent to Coder	System	29 Oct 2020 13:51:53
User entered 'Vitamin b12'	Cindy Lubbers (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 15:48:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 15:48:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	29 Oct 2020 15:48:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 13:51:45
User entered empty.	System	29 Oct 2020 13:51:45
	Cindy Lubbers (b) (4)	29 Oct 2020 13:51:45
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 15:48:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 15:48:02
User entered 'general health' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	29 Oct 2020 15:48:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 13:51:45
User entered empty.	System	29 Oct 2020 13:51:45
	Cindy Lubbers (b) (4)	29 Oct 2020 13:51:45
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '1000'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'ug (ug)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'once daily (QD)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '16 Oct 2020'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 15:48:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 15:48:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	29 Oct 2020 15:48:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 13:51:45
User entered empty.	System	29 Oct 2020 13:51:45
	Cindy Lubbers (b) (4)	29 Oct 2020 13:51:45
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:14:21
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 13:51:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 07:39:50
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' answered with 'Was sent home with this after hospitalization for PNA - not worsening allergies just to use when needed.' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	01 Feb 2021 21:30:35
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:09:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:26:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 04:26:10
Data point term sent to Coder	System	29 Oct 2020 13:54:58
User entered 'ipratropium nasal 21 mcg/inh (0.03%)'	Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 13:54:23

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'seasonal allergies'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '21'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'ug (ug)'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'twice daily (BID)'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Nasal (NASAL)'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '16 Oct 2020'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered 'No (N)'	Cindy Lubbers (b) (4)	29 Oct 2020 13:54:23
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Oct 2020 13:54:23

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 13:54:23

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 13:54:23

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 08:01:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 08:01:05
Data point term sent to Coder Coding entries removed.	System Cindy Lubbers (b) (4)	25 Jan 2021 22:29:04 25 Jan 2021 22:28:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:27:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:27:03
Data point term sent to Coder User entered 'Ibuprofen'	System Cindy Lubbers (b) (4)	29 Oct 2020 15:49:46 29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, leg pain, generalized pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 05:30:31
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 08:26:05
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, leg pain, generalized pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' answered with 'Corrected' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	25 Jan 2021 22:29:01

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' answered with 'This was recorded on diary after injection. The subject was admitted to the hospital 2 days later with CAP. It is listed as an SAE' (Site from DM).	Cindy Lubbers (b) (4)	25 Jan 2021 22:28:45
User entered 'joint PAIN/FEVER' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	25 Jan 2021 22:28:13
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, leg pain, generalized pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:50:50
Query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:50:46
User opened query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:26:44

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[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 timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:26:34
User entered 'pain/fever'	Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '200'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'as needed (PRN)'	Cindy Lubbers (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	Cindy Lubbers (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '8 Oct 2020'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Cindy Lubbers (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '8 Oct 2020'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User entered empty.	System	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User entered empty.	System	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:33
User entered empty.	System	29 Oct 2020 15:49:17

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
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)	25 Jan 2021 22:30:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 22:30:51
Data point term sent to Coder	System	25 Jan 2021 22:30:06
Coding entries removed.	Cindy Lubbers (b) (4)	25 Jan 2021 22:29:29
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)	30 Oct 2020 04:27:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:27:18
Data point term sent to Coder	System	29 Oct 2020 15:50:52
User entered 'Tylenol'	Cindy Lubbers (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, leg pain, generalized pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 05:30:41
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 08:27:38
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, leg pain, generalized pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' answered with 'done' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	25 Jan 2021 22:29:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' answered with 'This was recorded on diary after injection. The subject was admitted to the hospital 2 days later with CAP. It is listed as an SAE' (Site from DM).	Cindy Lubbers (b) (4) (b) (4)	25 Jan 2021 22:29:42
User entered 'joint PAIN/FEVER' reason for change: Data Entry Error	Cindy Lubbers (b) (4) (b) (4)	25 Jan 2021 22:29:29
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. Injection site pain, leg pain, generalized pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:50:16
Query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:50:11
User opened query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:27:33

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[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 timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:27:24
User entered 'pain/fever'	Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '325'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'as needed (PRN)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	Cindy Lubbers (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '8 Oct 2020'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '8 Oct 2020'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User entered empty.	System	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User entered empty.	System	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:39
User entered empty.	System	29 Oct 2020 15:50:45

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
User closed query 'please add other treatment for Pneumonia (starting from Acetaminophen 650 mg in ConMed Log)' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:10:23
Query 'please add other treatment for Pneumonia (starting from Acetaminophen 650 mg in ConMed Log)' answered with 'Completed' (Site from CRA).	Cindy Lubbers (b) (4)	09 Apr 2021 16:35:55
User opened query 'please add other treatment for Pneumonia (starting from Acetaminophen 650 mg in ConMed Log)' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:40:57
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 16:37:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 16:37:42
Data point term sent to Coder	System	29 Oct 2020 16:06:25
User entered 'Azithromycin'	Cindy Lubbers (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Pneumonia'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '500'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'once daily (QD)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Oral (ORAL)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
User closed query 'according to DS Pt completed 3 days on Azithromycin' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:19:01
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Query 'according to DS Pt completed 3 days on Azithromycin' answered with 'corrected' (Site from CRA).	(b) (4) Cindy Lubbers (b) (4)	30 Mar 2021 18:32:24
User opened query 'according to DS Pt completed 3 days on Azithromycin' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 16:30:13
User entered '10 Oct 2020'	(b) (4) Cindy Lubbers (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '12 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Cindy Lubbers (b) (4)	30 Mar 2021 18:32:16
User entered '11 Oct 2020'	(b) (4)	
	Cindy Lubbers (b) (4)	29 Oct 2020 16:05:48
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:17:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
User entered '1'	System	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
User entered '1'	System	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:49
User entered '804 (804)'	System	29 Oct 2020 16:05:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User closed query 'please add Cefdinir taken 12-14 Oct20' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:37:50
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Query 'please add Cefdinir taken 12-14 Oct20' answered with 'added' (Site from CRA).	Cindy Lubbers (b) (4)	30 Mar 2021 20:14:16
User opened query 'please add Cefdinir taken 12-14 Oct20' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 16:27:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 16:53:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 16:53:43
Data point term sent to Coder	System	29 Oct 2020 16:07:28
User entered 'ceftriaxone'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'pneumonia'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '2'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'g (g)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'once daily (QD)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Intravenous (INTRAVENOUS)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
	(b) (4)	
DataPoint Un-verified.	Laila Hussaini (b) (4)	20 Apr 2021 19:42:23
	(b) (4)	
Signature has been broken.	Laila Hussaini (b) (4)	20 Apr 2021 19:42:23
	(b) (4)	
User entered 'UN Oct 2020' reason for change: Data Entry Error	Laila Hussaini (b) (4)	20 Apr 2021 19:42:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '10 Oct 2020'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
	(b) (4)	
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	20 Apr 2021 19:42:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:51:43
User closed query 'please correct to Un Oct 2020 as per source ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:51:41
Query 'please correct to Un Oct 2020 as per source ' answered with 'corrected' (Site from CRA).	Cindy Lubbers (b) (4)	16 Apr 2021 13:52:13
	(b) (4)	
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	16 Apr 2021 13:52:06
User entered 'un Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	16 Apr 2021 13:52:06
	(b) (4)	
User opened query 'please correct to Un Oct 2020 as per source ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:02:38
Query 'please correct to Un as per source' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:02:26
User opened query 'please correct to Un as per source' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:02:20
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	13 Apr 2021 12:55:00
DataPoint Un-verified.	Cindy Lubbers (b) (4)	13 Apr 2021 12:55:00
	(b) (4)	
User entered '16 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	13 Apr 2021 12:55:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:46:54
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	12 Apr 2021 22:38:50
DataPoint Un-verified.	Kathy Stephens (b) (4)	12 Apr 2021 22:38:50
	(b) (4)	
Signature has been broken.	Kathy Stephens (b) (4)	12 Apr 2021 22:38:50
	(b) (4)	
User entered 'un Oct 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	12 Apr 2021 22:38:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	30 Mar 2021 19:20:39
User entered '11 Oct 2020'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:15:11
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Cindy Lubbers (b) (4)	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
User entered '1'	System	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
User entered '1'	System	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:12
User entered '804 (804)'	System	29 Oct 2020 16:07:22

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User closed query 'please add treatment prescribed for Toxic Encephalopathy' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:10:45
Query 'please add treatment prescribed for Toxic Encephalopathy' answered with 'There was no specific treatment for this - per medical records, it resolved with treatment of CAP' (Site from CRA).	Cindy Lubbers (b) (4)	09 Apr 2021 16:08:25
User opened query 'please add treatment prescribed for Toxic Encephalopathy' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:29:20
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:19:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Mar 2021 07:19:34
Data point term sent to Coder	System	30 Mar 2021 20:12:41
Data point term sent to Coder	System	30 Mar 2021 20:11:41
User entered 'Cefdinir'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'Community acquired pneumonia'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '300'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'mg (mg)'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 20:11:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 20:11:42
User entered 'twice daily (BID)' reason for change:	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:42
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 20:11:20
User entered empty.	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 20:11:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 20:11:51
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 20:11:20
User entered empty.	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered empty.	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '12 Oct 2020'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '0'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
Query 'End date is prior to start date. Please correct.' canceled (Site from System).	(b) (4), (b) (6)	15 Apr 2021 19:38:46
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:43:20
User closed query 'Please confirm if correct Stop Date should be "Un Oct 2020"' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:43:19
Query 'Please confirm if correct Stop Date should be "Un Oct 2020"' answered with 'Confirmed' (Site from CRA).	Kathy Stephens (b) (4)	13 Apr 2021 19:22:10
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	13 Apr 2021 19:21:55
DataPoint Un-verified.	Kathy Stephens (b) (4)	13 Apr 2021 19:21:55
User entered 'un Oct 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	13 Apr 2021 19:21:55
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:23
User opened query 'Please confirm if correct Stop Date should be "Un Oct 2020"' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:09:20
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	13 Apr 2021 12:57:26
DataPoint Un-verified.	Cindy Lubbers (b) (4)	13 Apr 2021 12:57:26
User entered '16 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	13 Apr 2021 12:57:26
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 22:46:32
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	12 Apr 2021 22:42:17
DataPoint Un-verified.	Kathy Stephens (b) (4)	12 Apr 2021 22:42:17
Signature has been broken.	Kathy Stephens (b) (4)	12 Apr 2021 22:42:17
User entered 'un Oct 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4)	12 Apr 2021 22:42:17
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
	(b) (4)	
User entered '14 Oct 2020'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:11:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'No (N)'	Cindy Lubbers (b) (4)	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
User entered '2'	System	30 Mar 2021 20:11:42
User entered empty.	System	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
User entered '1'	System	30 Mar 2021 20:11:42
User entered empty.	System	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:13
User entered '804 (804)'	System	30 Mar 2021 20:11:42
User entered empty.	System	30 Mar 2021 20:11:20

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
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)	09 Apr 2021 16:13:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:13:35
Data point term sent to Coder	System	09 Apr 2021 16:12:57
User entered 'Acetaminophen'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered 'General pain'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:11
User closed query 'please with source if should be 650' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:59:08
Query 'please with source if should be 650' answered with 'changed' (Site from CRA).	Kathy Stephens (b) (4)	12 Apr 2021 20:21:50
DataPoint Un-verified.	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:21:39
User entered '650' reason for change: Data Entry Error	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:21:39
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:42
User opened query 'please with source if should be 650' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:07:53
User entered '325'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered 'mg (mg)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:59:20
User closed query 'please with source if should be once a day' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 18:59:16
Query 'please with source if should be once a day' answered with 'updated' (Site from CRA).	Kathy Stephens (b) (4)	12 Apr 2021 20:23:54
DataPoint Un-verified.	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:21:39
User entered 'once daily (QD)' reason for change:	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:21:39
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:09:42
User opened query 'please with source if should be once a day' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:09:08
User entered 'as needed (PRN)'	Cindy Lubbers (b) (4)	09 Apr 2021 16:12:30
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered 'Oral (ORAL)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered '10 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered '16 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:09:42
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User entered '1'	System	12 Apr 2021 20:21:39
User entered empty.	System	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User entered '1'	System	12 Apr 2021 20:21:39
User entered empty.	System	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:04
User entered '804 (804)'	System	12 Apr 2021 20:21:39
User entered empty.	System	09 Apr 2021 16:12:30

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 10:15:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:15:49
Data point term sent to Coder	System	12 Apr 2021 20:28:18
Coding entries removed.	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 20:27:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:20:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:20:46
Data point term sent to Coder	System	09 Apr 2021 16:20:15
User entered 'Enoxaparin'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered 'Prevention of DVT'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered '40'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered 'mg (mg)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered 'once daily (QD)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:03:20
User closed query 'please check with source' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:03:17
Query 'please check with source' answered with 'updated' (Site from CRA).	Kathy Stephens (b) (4)	12 Apr 2021 20:27:34
DataPoint Un-verified.	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:27:22
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:27:22
User opened query 'please check with source' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:17:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered 'Intravenous (INTRAVENOUS)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered '10 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered '16 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:16:11
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User entered '1'	System	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User entered '1'	System	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:11
User entered '804 (804)'	System	09 Apr 2021 16:19:24

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:23:35
Data point term sent to Coder Coding entries removed.	System Kathy Stephens (b) (4)	12 Apr 2021 20:33:30 12 Apr 2021 20:33:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:00:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:00:58
Data point term sent to Coder User entered 'metoprolol XL'	System Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:24:21 09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:10:13
DataPoint Un-verified.	Kathy Stephens (b) (4)	12 Apr 2021 20:33:20
User entered 'hypertension' reason for change: Data Entry Error	Kathy Stephens (b) (4)	12 Apr 2021 20:33:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered 'Blood pressure'	Cindy Lubbers (b) (4)	09 Apr 2021 16:23:48
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered '25'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered 'mg (mg)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered 'once daily (QD)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered 'Oral (ORAL)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered '10 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered '16 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:22
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User entered '1'	System	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User entered '1'	System	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:18
User entered '804 (804)'	System	09 Apr 2021 16:23:48

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:26:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:26:47
Data point term sent to Coder	System	09 Apr 2021 16:26:27
User entered 'Ondansetron'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User closed query 'please check if it was Prophylaxis' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:10:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:10:20
Query 'please check if it was Prophylaxis' answered with 'updated' (Site from CRA).	Kathy Stephens (b) (4)	12 Apr 2021 20:30:19
DataPoint Un-verified.	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:29:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:29:43
User opened query 'please check if it was Prophylaxis' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:21:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User closed query 'please check with source' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:10:26
Query 'please check with source' answered with 'done' (Site from CRA).	Kathy Stephens (b) (4)	12 Apr 2021 20:30:25
User opened query 'please check with source' (Site from CRA).	(b) (4)	12 Apr 2021 15:20:07
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered 'nausea and vomiting'	Cindy Lubbers (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered '4'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered 'mg (mg)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User closed query 'please check as 3 times/day per source' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:10:45
Query 'please check as 3 times/day per source' answered with 'updated source' (Site from CRA).	Kathy Stephens (b) (4)	12 Apr 2021 20:31:14
User opened query 'please check as 3 times/day per source' (Site from CRA).	(b) (4)	12 Apr 2021 15:22:03
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered 'as needed (PRN)'	Cindy Lubbers (b) (4)	09 Apr 2021 16:25:43
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered 'Oral (ORAL)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered '10 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered '16 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:18:52
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User entered empty.	System	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User entered empty.	System	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:25
User entered empty.	System	09 Apr 2021 16:25:43

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:23:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:23:36
Data point term sent to Coder Coding entries removed.	System Kathy Stephens (b) (4)	12 Apr 2021 20:34:33 12 Apr 2021 20:33:54
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 16:29:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 16:29:46
Data point term sent to Coder User entered 'Valsartan'	System Cindy Lubbers (b) (4)	09 Apr 2021 16:28:30 09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:10:57
DataPoint Un-verified.	Kathy Stephens (b) (4)	12 Apr 2021 20:33:54
User entered 'hypertension' reason for change: Data Entry Error	Kathy Stephens (b) (4)	12 Apr 2021 20:33:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered 'Blood pressure'	Cindy Lubbers (b) (4)	09 Apr 2021 16:28:04
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User closed query 'please check with source if should be 80' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:02
Query 'please check with source if should be 80' answered with 'done' (Site from CRA).	Kathy Stephens (b) (4)	12 Apr 2021 20:34:35
DataPoint Un-verified.	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:34:28
User entered '80' reason for change: Data Entry Error	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 20:34:28
User opened query 'please check with source if should be 80' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:23:27
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered '11'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User closed query 'please check with source if should be mg' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:06
Query 'please check with source if should be mg' answered with 'done' (Site from CRA).	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 20:34:40
DataPoint Un-verified.	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 20:34:28
User entered 'mg (mg)' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 20:34:28
User opened query 'please check with source if should be mg' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:23:44
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered 'Other (OTHER)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User closed query 'please check with source if should be empty' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:11:13
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:11
Query 'please check with source if should be empty' answered with 'done' (Site from CRA).	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 20:34:46
DataPoint Un-verified.	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 20:34:28
User entered empty; reason for change Data Entry Error	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 20:34:28
User opened query 'please check with source if should be empty' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 15:23:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered '2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered 'once daily (QD)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered 'Oral (ORAL)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered '11 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered '0'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered '16 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:22:32
User entered 'No (N)'	Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User entered '1'	System	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User entered '1'	System	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:32
User entered '804 (804)'	System	09 Apr 2021 16:28:04

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:55:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 08:55:45
Data point term sent to Coder	System	12 Apr 2021 21:15:56
Data point term sent to Coder	System	12 Apr 2021 21:14:55
User entered 'shingrix dose 1'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered 'Yes (Y)'	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Apr 2021 21:15:54
User entered 'prevent shingles' reason for change: Data Entry Error	Kathy Stephens (b) (4)	12 Apr 2021 21:15:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	12 Apr 2021 21:14:52
	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered '0.5'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered 'mL (mL)'	(b) (4) Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered empty.	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered 'once (ONCE)'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered empty.	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered 'Intramuscular (INTRAMUSCULAR)'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered empty.	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered '18 Jan 2021'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered '0'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered 'No (N)'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered '18 Jan 2021'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User entered 'No (N)'	Kathy Stephens (b) (4)	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User entered empty.	System	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User entered empty.	System	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:40
User entered empty.	System	12 Apr 2021 21:14:52

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 05:20:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 05:20:59
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN, PRODUCTSYNONYM: B-12 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 05:09:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 05:09:08
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	22 Apr 2021 15:18:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: CYANOCOBALAMIN, PRODUCTSYNONYM: B-12 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:10:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:10:45
Data point term sent to Coder	System	16 Apr 2021 13:55:30
Coding entries removed.	Cindy Lubbers (b) (4) (b) (4)	16 Apr 2021 13:54:50

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: HOMEOPATHIC PREPARATION, PRODUCT: CYANOCOBALAMIN, PRODUCTSYNONYM: B-12 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:05:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:05:41
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:15:25
Data point term sent to Coder	System	12 Apr 2021 21:22:01
User entered 'B-12'	Kathy Stephens (b) (4)	12 Apr 2021 21:21:27
	(b) (4)	

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:52:20
DataPoint Un-verified.	Cindy Lubbers (b) (4)	16 Apr 2021 13:54:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Cindy Lubbers (b) (4)	16 Apr 2021 13:54:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
User closed query 'please check if should be changed to Prophylaxis - General Health' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:52:22
Query 'please check if should be changed to Prophylaxis - General Health' answered with 'Corrected' (Site from CRA).	Cindy Lubbers (b) (4)	16 Apr 2021 13:54:57
DataPoint Un-verified.	(b) (4) Cindy Lubbers (b) (4)	16 Apr 2021 13:54:50
User entered 'General health' reason for change:	Cindy Lubbers (b) (4)	16 Apr 2021 13:54:50
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:15:25
User opened query 'please check if should be changed to Prophylaxis - General Health' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:12:23
User entered 'Community acquired pneumonia'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered '1000'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered 'ug (ug)'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered empty.	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered 'once (ONCE)'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered empty.	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered 'Intramuscular (INTRAMUSCULAR)'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered empty.	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered '11 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered '0'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered '11 Oct 2020'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User signature succeeded.	Evan Anderson (b) (4)	22 Apr 2021 15:18:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 19:15:25
User entered 'No (N)'	Kathy Stephens (b) (4) (b) (4)	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User entered empty.	System	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User entered empty.	System	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:05:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:46
User entered empty.	System	12 Apr 2021 21:21:27

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:05:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:42:00
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:51:59
User entered 'Yes (Y)'	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:15:22

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:05:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:53:01
User entered '10 Oct 2020'	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:16:12

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:05:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:53:01
User entered 'Chest x-ray'	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:16:12

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:53:01
User entered 'Adverse Event (AE)'	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:16:12

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:05:38

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:53:01
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:16:12

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:05:38

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:41
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:35
User closed query 'please check if should be 14Oct20(page 59 of DS)' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:07:33
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
Query 'please check if should be 14Oct20(page 59 of DS)' answered with 'corrected' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Cindy Lubbers (b) (4)	09 Apr 2021 20:49:39
	(b) (4)	
	Cindy Lubbers (b) (4)	09 Apr 2021 20:49:32
	(b) (4)	
User entered '14 Oct 2020' reason for change: Data Entry Error	Cindy Lubbers (b) (4)	09 Apr 2021 20:49:32
	(b) (4)	
User opened query 'please check if should be 14Oct20(page 59 of DS)' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 17:54:40
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:53:00
	(b) (4)	
User entered '10 Oct 2020'	Cindy Lubbers (b) (4)	04 Jan 2021 20:16:50
	(b) (4)	

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:05:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:41
User closed query 'Please add Viral and Bacterial studies performed 10Oct20 for AE' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:07:39
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
Query 'Please add Viral and Bacterial studies performed 10Oct20 for AE' answered with 'added' (Site from CRA).	(b) (4) Cindy Lubbers (b) (4)	09 Apr 2021 20:50:51
User opened query 'Please add Viral and Bacterial studies performed 10Oct20 for AE' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 17:55:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:53:00
User entered 'Abdominal ultrasound'	Cindy Lubbers (b) (4)	04 Jan 2021 20:16:50

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:53:00
User entered 'Adverse Event (AE)'	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:16:50

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:05:38

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:53:00
User entered empty.	Cindy Lubbers (b) (4) (b) (4)	04 Jan 2021 20:16:50

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:05:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:50
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
User entered '10 Oct 2020'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 20:50:14

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:05:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:50
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
User entered 'Bacterial study'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 20:50:14

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:50
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
User entered 'Adverse Event (AE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 20:50:14

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:05:38

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:47
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:50
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 20:50:14

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:05:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:53
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
User entered '10 Oct 2020'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 20:50:36

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:05:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:53
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
User entered 'Viral studies'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 20:50:36

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:05:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:53
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
User entered 'Adverse Event (AE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 20:50:36

US3532231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:05:38

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:33:51
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:07:53
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:39:03
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	09 Apr 2021 20:50:36

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'USA-US077-2020-MRNA-1273-P301000004'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Evan'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Anderson'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '2015 Uppergate Drive'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Atlanta'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'GA'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '30323'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:00:44
User entered 'US'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Nov 2020 17:09:32
User entered '3'	System	28 Oct 2020 16:03:16
User entered '2'	System	20 Oct 2020 14:00:55
User entered '1'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'USA-US077-2020-MRNA-1273-P301000004'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Evan'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Anderson'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '2015 Uppergate Drive'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Atlanta'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'GA'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '30323'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:00:44
User entered 'US'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Nov 2020 17:09:32
User entered '3'	System	28 Oct 2020 16:03:16
User entered '2'	System	20 Oct 2020 14:00:55
User entered '1'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:05:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '12/Oct/2020 15:55'	(b) (4) System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:05:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:00:44
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'USA-US077-2020-MRNA-1273-P301000004'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Evan'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Anderson'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '2015 Uppergate Drive'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Atlanta'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'GA'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '30323'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:00:44
User entered 'US'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Nov 2020 17:09:32
User entered '3'	System	28 Oct 2020 16:03:16
User entered '2'	System	20 Oct 2020 14:00:55
User entered '1'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:05:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '20/Oct/2020 14:00'	(b) (4) System	20 Oct 2020 14:00:55

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:05:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:55
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 14:00:55

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'USA-US077-2020-MRNA-1273-P301000004'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Evan'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Anderson'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '2015 Uppergate Drive'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Atlanta'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'GA'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '30323'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:00:44
User entered 'US'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Nov 2020 17:09:32
User entered '3'	System	28 Oct 2020 16:03:16
User entered '2'	System	20 Oct 2020 14:00:55
User entered '1'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:05:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '28/Oct/2020 12:03'	(b) (4) System	28 Oct 2020 16:03:16

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:05:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:56:41
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 16:03:16

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'USA-US077-2020-MRNA-1273-P301000004'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Evan'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Anderson'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '2015 Uppergate Drive'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Atlanta'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'GA'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '30323'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:00:44
User entered 'US'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Nov 2020 17:09:32
User entered '3'	System	28 Oct 2020 16:03:16
User entered '2'	System	20 Oct 2020 14:00:55
User entered '1'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:05:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '11/Nov/2020 12:09'	(b) (4) System	11 Nov 2020 17:09:32

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:05:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:09:32

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'USA-US077-2020-MRNA-1273-P301000004'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Yes (Y)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'No (N)'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Evan'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Anderson'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '2015 Uppergate Drive'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'Atlanta'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered 'GA'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:54:59
User entered '30323'	System	12 Oct 2020 15:54:38

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 14:00:44
User entered 'US'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:05:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Nov 2020 17:09:32
User entered '3'	System	28 Oct 2020 16:03:16
User entered '2'	System	20 Oct 2020 14:00:55
User entered '1'	System	12 Oct 2020 15:55:06

US3532231

Folder: SAE USA-US077-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:05:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:35:48
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:49:33
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:09:32