

US3532002 (Prod: Children's Healthcare of Atlanta)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:06:59

All time stamps listed in this document are displayed in GMT

US3532002

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 19:58:41

Generated On: 10 Jun 2021 08:06:59

[Participant ID](#)

US3532002

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

US3532002

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:58:43

Generated On: 10 Jun 2021 08:06:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	63
Age Units	YEARS
Age (Derived)	64
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 19:58:42

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Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 19:58:43

Generated On: 10 Jun 2021 08:06:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 19:58:43

Generated On: 10 Jun 2021 08:06:59

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	HYPERTENSION
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 (2)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	ELEVATED CHOLESTEROL
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 (5)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	BACK SURGERY LUMBAR LAMINECTOMY
Start date (dd MMM yyyy)	UN DEC 2019
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 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	RIGHT ROTATOR CUFF TEAR
Start date (dd MMM yyyy)	UN UNK 2004
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	RIGHT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	RIGHT KNEE SCOPE
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	RIGHT BROKEN FEMUR
Start date (dd MMM yyyy)	UN UNK 1976
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	RIGHT FEMUR LENGTHENING SURGERY
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	BILATERAL 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 SEP 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	SEP 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	BILATERAL CATARACT SURGERIES
Start date (dd MMM yyyy)	UN SEP 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 SEP 2018
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	SEP 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	HYPOTHYROIDISM
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 (15)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	TORN CARTILAGE IN RIGHT KNEE
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

Condition	ROSACEA
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)	_____

US3532002

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 27 Mar 2021 09:14:23

Generated On: 10 Jun 2021 08:06:59

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:58:43

Generated On: 10 Jun 2021 08:06:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:11 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:11
Height (<i>xxx.x</i>)	174 cm
Weight (<i>xxx.x</i>)	85.5 kg
BMI (<i>xxx.x</i>)	28.24019 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:58:43

Generated On: 10 Jun 2021 08:06:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 19:58:43

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

ENGINEER-PERFORMS SITE
INSPECTIONS 3X/WEEK

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) 12 Feb 2021 19:58:43

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 143706

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 19:59:03

Generated On: 10 Jun 2021 08:06:59

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 19:59:03

Generated On: 10 Jun 2021 08:06:59

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)	11 AUG 2020
Time of assessment (00:00-23:59)	15:11 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:11
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

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)	11 AUG 2020
Time of assessment (00:00-23:59)	17:51 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 17:51
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 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 19:59:03

Generated On: 10 Jun 2021 08:06:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:58:43

Generated On: 10 Jun 2021 08:06:59

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 17:21 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 17:21

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	16:49 (24 HR)
Collection date and time (derived)	11 AUG 2020 16:49

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:58:43

Generated On: 10 Jun 2021 08:06:59

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:35	11 AUG 2020 16:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:43

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 18:17

PC Open Date & Time

11 AUG 2020 17:41

PC Close Date & Time

11 AUG 2020 20:11

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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 97.6 °F

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

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

PC Time Stamp	11 AUG 2020 21:29
PC Open Date & Time	11 AUG 2020 21:06
PC Close Date & Time	12 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:18

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 16:35

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

14 AUG 2020 18:21

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 18:10

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

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

16 AUG 2020 19:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

17 AUG 2020 17:32

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

11 AUG 2020 18:18

PC Open Date & Time

11 AUG 2020 17:41

PC Close Date & Time

11 AUG 2020 20:11

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 21:32

PC Open Date & Time

11 AUG 2020 21:06

PC Close Date & Time

12 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:20

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

25

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 16:36

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

14 AUG 2020 18:22

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

15 AUG 2020 18:11

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

16 AUG 2020 19:42

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

17 AUG 2020 17:33

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 18:19
PC Open Date & Time	11 AUG 2020 17:41
PC Close Date & Time	11 AUG 2020 20:11

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 21:33
PC Open Date & Time	11 AUG 2020 21:06
PC Close Date & Time	12 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

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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US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:22
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

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)

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 16:37
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

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 ☒

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 18:23
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

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)

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

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 ☒

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EAB) (1725)

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US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 19:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

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)

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 17:33
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3532002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

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)	8 SEP 2020
Time of assessment (00:00-23:59)	07:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 07:40
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

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)	8 SEP 2020
Time of assessment (00:00-23:59)	09:12 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 09:12
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3532002

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 08:40 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 08:40

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

US3532002

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	08:07 (24 HR)
Collection date and time (derived)	8 SEP 2020 08:07

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:51	8 SEP 2020 07:51
Nasopharyngeal Swab 2	No		

US3532002

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 09:16

PC Open Date & Time

08 SEP 2020 09:00

PC Close Date & Time

08 SEP 2020 11:30

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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 97.6 °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 19:06
PC Open Date & Time	08 SEP 2020 12:25
PC Close Date & Time	09 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 16:12

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 21:34

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 16:56

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

13 SEP 2020 18:56

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

14 SEP 2020 18:07

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 09:16

PC Open Date & Time

08 SEP 2020 09:00

PC Close Date & Time

08 SEP 2020 11:30

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

4

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:12

PC Open Date & Time

08 SEP 2020 12:25

PC Close Date & Time

09 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 16:56

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

5

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 16:13

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 21:36

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 16:56

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:56

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

14 SEP 2020 18:07

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 09:17
PC Open Date & Time	08 SEP 2020 09:00
PC Close Date & Time	08 SEP 2020 11:30

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 19:13
PC Open Date & Time	08 SEP 2020 12:25
PC Close Date & Time	09 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

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)

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:57
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

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 ☒

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 16:14
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 21:36
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 16:57
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:57
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:08
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3532002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:33 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 12:33
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532002

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

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.

US3532002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 OCT 2020
Collection time (00:00-23:59)	12:47 (24 HR)
Collection date and time (derived)	12 OCT 2020 12:47

US3532002

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:59:03

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 20:27:53
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

18 OCT 2020 00:02:18

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 14:15:48

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 15:16:35
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 18:53:04
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 18:59:04

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 18:36:41
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

03 DEC 2020 06:15:27

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 10:25:36
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 06:04:09

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

24 DEC 2020 03:58:26

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

04 JAN 2021 18:55:25

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

07 JAN 2021 08:00:56

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 16:29:15

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 JAN 2021 07:19:05
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

29 JAN 2021 12:20:01

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

11 FEB 2021 22:48:09

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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	18 FEB 2021 10:16:26
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

25 FEB 2021 09:11:41

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

04 MAR 2021 07:00:39

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

12 MAR 2021 13:36:28

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

18 MAR 2021 07:55:56

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 MAR 2021 11:36:53
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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	01 APR 2021 09:23:35
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 12:42:52

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 13:32:49

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 18:31:15

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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="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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 <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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 <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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 <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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 <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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 <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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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="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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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="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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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°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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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 ☐

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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"/>

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3532002

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:06:59

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 20:10:10

US3532002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

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) _____

US3532002

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

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.

US3532002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 MAR 2021
Collection time (00:00-23:59)	14:58 (24 HR)
Collection date and time (derived)	9 MAR 2021 14:58

US3532002

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 08:34:33

Generated On: 10 Jun 2021 08:06:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3532002

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 08:34:33

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532002

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532002

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:06:59

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

US3532002

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:06:59

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3532002

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

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

Visit date (dd MMM yyyy)	11 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3532002

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Date of updated informed consent (*dd MMM yyyy*) 11 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*) 11 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 _____

US3532002

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	15:40 (24 HR)
Collection date and time (derived)	11 JAN 2021 15:40

US3532002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

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

Collection date (dd MMM yyyy)	11 JAN 2021
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Collection time (00:00 - 23:59)	15:21
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Collection Date and Time (derived)	11 JAN 2021 15:21
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US3532002

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 19:58:41

Generated On: 10 Jun 2021 08:06:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

AEID

Adverse event

WORSENING BACK PAIN

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)

20 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 SEP 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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____ _____

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

AEID	USA-US077-2020-MRNA-1273-P30 1000003
Adverse event	WORSENING BACK PAIN
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)	8 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)	14 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)	16 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	18 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

DUE TO UNDERLYING BACK
PROBLEMS AND UNRELATED
TO VACCINE. HE HAD A
TRANSFORAMINAL LUMBER
INTERBODY FUSION OF HIS
SPINE DUE TO DEGENERATIVE
DISK DISEASE IN HIS BACK (AN
UNDERLYING MEDICAL
HISTORY PROBLEM).
HOSPITALIZED AFTER
SURGERY.

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

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

AEID

Adverse event

WORSENING ROSACEA

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)

15 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)

15 DEC 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) 19 Mar 2021 09:04:54

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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	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	NOT RELATED. UNDERLYING MEDICAL PROBLEM THAT IS WORSE.
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 (4)

Data signed: (b) (4) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

AEID

Adverse event

SQUAMOUS CELL CARCINOMA

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)

8 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 DEC 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) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

AEID	
Adverse event	WORSENING HYPERTENSION
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)	12 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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 (5)

Data signed: (b) (4) 19 Mar 2021 09:04:54

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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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PHYSICIAN INCREASED CARVEDILOL CURRENTLY TAKEN FOR HYPERTENSION.
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) 19 Mar 2021 09:04:54

Generated On: 10 Jun 2021 08:06:59

AEID	
Adverse event	WORSENING HYPOTHYROIDISM
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)	12 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 19 Mar 2021 09:04:54

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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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PHYSICIAN INCREASED LEVOTHYROXINE WHICH HE IS CURRENTLY TAKING FOR HYPOTHYROIDISM.
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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 19:58:42

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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) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication ELEVATED CHOLESTEROL

Dose per administration 145

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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)		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) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 6.25

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 (2)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 2021
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 (3)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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)		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) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication BABY ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL 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 (5)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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 (6)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication ELEVATED 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 (6)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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)		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) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication OZEMPIC

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

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 (7)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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 checked="" type="radio"/>
	804	<input type="radio"/>

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 750

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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US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

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) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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 1985	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
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 (10)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration UNKNOWN

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) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 SEP 2020		
Was this medication taken for solicited event?	Yes	<input 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"/>

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication METHOCARBOMOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 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"/>

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication WORSENING BACK PAIN

Dose per administration 10/325

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

EVERY 6 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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)	17 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication ANNUAL VACCINE

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 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"/>

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING ROSACEA

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 (14)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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)	8 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 JAN 2021
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"/>

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING HYPERTENSION

Dose per administration 12.5

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 (15)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING
HYPOTHYROIDISM

Dose per administration 75

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 18:42:30

Generated On: 10 Jun 2021 08:06:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 SEP 2020	TRANSFORAMINAL LUMBAR INTERBODY FUSION	Adverse Event	
10 NOV 2020	REOCCURRING PHYSICAL THERAPY	Other	RELATED TO RECENT BACK SURGERY
29 DEC 2020	SQUAMOUS CELL REMOVAL	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:06:59

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 08:06:59

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 ☐

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

SAEID	USA-US077-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

SAEID	USA-US077-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	23/SEP/2020 08:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

SAEID	USA-US077-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	21/OCT/2020 17:45
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

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

SAEID	USA-US077-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	26/OCT/2020 15:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

SAEID	USA-US077-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	29/OCT/2020 19:04
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

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Feb 2021 19:58:42

Generated On: 10 Jun 2021 08:06:59

SAEID	USA-US077-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	03/NOV/2020 08:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3532002 (Prod: Children's Healthcare of Atlanta)

US3532002

Form: Participant Creation

Generated On: 10 Jun 2021 08:06:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'US3532002'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 18:49:45

US3532002

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 19:43:53

US3532002

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 18:49:46

US3532002

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Clinic (Clinic)'	Etza Peters (b) (4)	11 Aug 2020 19:43:53

US3532002

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'SCRN'	System	11 Aug 2020 19:43:53

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 18:49:47

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '63'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'YEARS'	System	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '64'	System	11 Aug 2020 19:45:05

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Male (M)'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'I'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:06:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 19:44:11

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Aug 2020'	Etza Peters (b) (4)	11 Aug 2020 19:45:05

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Aug 2020'	System	11 Aug 2020 19:45:05

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2020'	System	11 Aug 2020 19:45:05

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Amendment 2 (2)'	Etza Peters (b) (4)	11 Aug 2020 19:45:05

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 22:06:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 22:06:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 22:06:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 19:45:05
User entered empty.	System	11 Aug 2020 19:45:05
	Etza Peters (b) (4)	11 Aug 2020 19:45:05
	(b) (4)	

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 19:45:05

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 19:45:05

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 19:45:05

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 18:49:46

US3532002

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:06:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1'	System	11 Aug 2020 22:06:44
User entered empty.	System	11 Aug 2020 21:50:24

US3532002

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 21:50:24

US3532002

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:06:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:46:30

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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)	11 Aug 2020 22:49:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:49:12
Data point term sent to Coder	System	11 Aug 2020 22:48:19
User entered 'Hypertension'	Etza Peters (b) (4)	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1990'	Etza Peters (b) (4)	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1990'	System	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1990'	System	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 22:47:24

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:49:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:49:12
Data point term sent to Coder	System	11 Aug 2020 22:48:20
User entered 'Type 2 Diabetes'	Etza Peters (b) (4)	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 2012'	Etza Peters (b) (4)	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 2012'	System	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2012'	System	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 22:47:54

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 06:32:26
User coded data point as SOC: Eye disorders, HLGT: Coder Import (b) (4) Glaucoma and ocular hypertension, HLT: Glaucomas (b) (4) (excl congenital), PT: Glaucoma, LLT: Glaucoma both eyes - version MedDRA\\23.0.	(b) (4)	26 Oct 2020 19:21:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:21:31
Data point term sent to Coder	System	26 Oct 2020 18:15:07
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:14:24
Coding entries removed.	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:14:18
User entered 'Bilateral GLAUCOMA' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:14:18
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:41:02
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'N meds taken' (Site from DM).	Etza Peters (b) (4) (b) (4)	20 Oct 2020 16:44:18

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:49:34
User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:47:31
User coded data point as SOC: Eye disorders, HLGT: Coder Import Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	(b) (4)	11 Aug 2020 22:50:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:50:13
Data point term sent to Coder	System	11 Aug 2020 22:49:21
User entered 'Glaucoma'	Etza Peters (b) (4)	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1977'	Etza Peters (b) (4)	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1977'	System	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1977'	System	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 22:48:23

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: Cholesterol high - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:51:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:51:14
Data point term sent to Coder	System	11 Aug 2020 22:50:24
User entered 'Elevated Cholesterol'	Etza Peters (b) (4)	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1990'	Etza Peters (b) (4)	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1990'	System	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1990'	System	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 22:49:25

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:51:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:51:14
Data point term sent to Coder	System	11 Aug 2020 22:50:24
User entered 'Vasectomy'	Etza Peters (b) (4)	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1996'	Etza Peters (b) (4)	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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)	22 Oct 2020 05:42:21
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 'updated' (Site from DM).	Etza Peters (b) (4) (b) (4)	20 Oct 2020 16:43:13
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	20 Oct 2020 16:42:42
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)	29 Sep 2020 10:51:38
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1996' reason for change:	(b) (4)	
Data Entry Error	Etza Peters (b) (4)	20 Oct 2020 16:42:42
User entered empty.	(b) (4)	
	Etza Peters (b) (4)	11 Aug 2020 22:49:48
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1996'	System	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1996'	System	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1996'	System	20 Oct 2020 16:42:42
User entered empty.	System	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1996'	System	20 Oct 2020 16:42:42
User entered empty.	System	11 Aug 2020 22:49:48

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal laminectomy, LLT: Lumbar laminectomy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 10:28:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 10:28:28
Data point term sent to Coder	System	11 Aug 2020 22:52:25
User entered 'Back Surgery Lumbar Laminectomy'	Etza Peters (b) (4)	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un Dec 2019'	Etza Peters (b) (4)	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:02:27
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un Dec 2019' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:02:27
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Dec 2019'	System	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2019'	System	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Dec 2019'	System	11 Aug 2020 23:02:27
User entered empty.	System	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2019'	System	11 Aug 2020 23:02:27
User entered empty.	System	11 Aug 2020 22:51:39

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 07:09:47
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) (b) (4)	26 Oct 2020 19:21:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:21:32
Data point term sent to Coder	System	26 Oct 2020 18:15:08
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:14:46
Coding entries removed.	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:14:41
User entered 'Right ROTATOR CUFF TEAR' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:14:41
User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:51:23
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) (b) (4)	11 Aug 2020 23:20:15

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Aug 2020 23:20:15
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 23:19:05
User entered 'Rotator Cuff Tear'	Etza Peters (b) (4)	11 Aug 2020 23:18:47
	(b) (4)	

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 2004'	Etza Peters (b) (4)	11 Aug 2020 23:18:47

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:18:47

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:19:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 23:19:58
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:19:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:18:47
User entered empty.	System	11 Aug 2020 23:18:47
	Etza Peters (b) (4)	11 Aug 2020 23:18:47
	(b) (4)	

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 2005'	Etza Peters (b) (4)	11 Aug 2020 23:18:47

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:18:47

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 2004'	System	11 Aug 2020 23:18:47

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2004'	System	11 Aug 2020 23:18:47

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 2005'	System	11 Aug 2020 23:18:47

US3532002

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2005'	System	11 Aug 2020 23:18:47

US3532002

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 07:09:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:21:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:21:32
Data point term sent to Coder	System	26 Oct 2020 18:16:09
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:15:34
Coding entries removed.	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:15:27
User entered 'Right ROTATOR CUFF REPAIR' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:15:27
User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral ROTATOR CUFF. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:51:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:21:16

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Aug 2020 23:21:16
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 23:20:06
Coding entries removed.	Etza Peters (b) (4)	11 Aug 2020 23:19:22
	(b) (4)	
User entered 'ROTATOR CUFF Repair' reason for	Etza Peters (b) (4)	11 Aug 2020 23:19:22
change: Data Entry Error	(b) (4)	
User coded data point as SOC: Musculoskeletal and	Coder Import (b) (4)	11 Aug 2020 23:05:17
connective tissue disorders, HLGT: Joint disorders,	(b) (4)	
HLT: Joint related disorders NEC, PT: Rotator cuff		
syndrome, LLT: Rotator cuff tear - version		
MedDRA\\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Aug 2020 23:05:17
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 23:03:41
User entered 'Rotator Cuff Tear'	Etza Peters (b) (4)	11 Aug 2020 23:03:30
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'UN UNK 2005' reason for change:	Etza Peters (b) (4)	11 Aug 2020 23:19:22
Data Entry Error	(b) (4)	
User entered 'un UNK 2004'	Etza Peters (b) (4)	11 Aug 2020 23:03:30
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:03:30

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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	11 Aug 2020 23:19:36
User entered 'No (N)' reason for change: Data Entry Error	System	11 Aug 2020 23:19:36
User opened query 'Data is required. Please complete.' (Site from System).	Etza Peters (b) (4)	11 Aug 2020 23:19:36
User entered empty.	(b) (4)	
	System	11 Aug 2020 23:03:30
	Etza Peters (b) (4)	11 Aug 2020 23:03:30
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 2005'	Etza Peters (b) (4)	11 Aug 2020 23:03:30

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:03:30

US3532002

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 2005'	System	11 Aug 2020 23:19:22
User entered 'Jan 2004'	System	11 Aug 2020 23:03:30

US3532002

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2005'	System	11 Aug 2020 23:19:22
User entered '2004'	System	11 Aug 2020 23:03:30

US3532002

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 2005'	System	11 Aug 2020 23:03:30

US3532002

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2005'	System	11 Aug 2020 23:03:30

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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) (4), (b) (6)	28 Oct 2020 07:44:06
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 'will update' (Site from DM).	Etza Peters (b) (4) (b) (4)	26 Oct 2020 18:15:59
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)	29 Sep 2020 10:50:37
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy R knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:07:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:07:15
Data point term sent to Coder	System	11 Aug 2020 23:06:47
User entered 'Right Knee Scope'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:06:04

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1984'	Etza Peters (b) (4)	11 Aug 2020 23:06:04

US3532002

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:06:04

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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	11 Aug 2020 23:20:17
User entered 'No (N)' reason for change: Data Entry Error	System	11 Aug 2020 23:20:17
User opened query 'Data is required. Please complete.' (Site from System).	Etza Peters (b) (4)	11 Aug 2020 23:20:17
User entered empty.	(b) (4)	
	System	11 Aug 2020 23:06:04
	Etza Peters (b) (4)	11 Aug 2020 23:06:04
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1984'	Etza Peters (b) (4)	11 Aug 2020 23:06:04

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:06:04

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1984'	System	11 Aug 2020 23:06:04

US3532002

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1984'	System	11 Aug 2020 23:06:04

US3532002

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1984'	System	11 Aug 2020 23:06:04

US3532002

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1984'	System	11 Aug 2020 23:06:04

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Femur fracture - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 14:56:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 14:56:47
User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:47:59
Data point term sent to Coder	System	20 Oct 2020 16:49:31
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Etza Peters (b) (4)	20 Oct 2020 16:48:52
Coding entries removed.	Etza Peters (b) (4)	20 Oct 2020 16:48:46
User entered 'Right BROKEN FEMUR' reason for change: Data Entry Error	Etza Peters (b) (4)	20 Oct 2020 16:48:46
User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:44:51
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Fracture femur - version MedDRA\23.0.	Coder Import (b) (4)	12 Aug 2020 12:31:29

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder User entered 'Broken Femur'	Coder Import (b) (4) (b) (4) System Etza Peters (b) (4) (b) (4)	12 Aug 2020 12:31:29 11 Aug 2020 23:08:48 11 Aug 2020 23:08:07

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1976'	Etza Peters (b) (4)	11 Aug 2020 23:08:07

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:08:07

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:20:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 23:20:38
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:20:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:08:07
User entered empty.	System	11 Aug 2020 23:08:07
	Etza Peters (b) (4)	11 Aug 2020 23:08:07
	(b) (4)	

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 23:22:26
User entered empty; reason for change Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:22:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 23:08:07
User entered 'un UNK ' (non-conformant).	Etza Peters (b) (4)	11 Aug 2020 23:08:07

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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'I'	Etza Peters (b) (4)	11 Aug 2020 23:08:07

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1976'	System	11 Aug 2020 23:08:07

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1976'	System	11 Aug 2020 23:08:07

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 23:08:07

US3532002

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 23:08:07

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone operation, LLT: Bone operation - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 14:44:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 14:44:50
User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:41:26
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)	22 Oct 2020 04:16:45
Data point term sent to Coder	System	20 Oct 2020 16:50:34
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 'in med hx' (Site from DM).	Etza Peters (b) (4)	20 Oct 2020 16:50:27
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated ' (Site from DM).	Etza Peters (b) (4)	20 Oct 2020 16:50:20
Coding entries removed.	Etza Peters (b) (4)	20 Oct 2020 16:50:14
User entered 'Right FEMUR LENGTHENING SURGERY' reason for change: Data Entry Error	Etza Peters (b) (4)	20 Oct 2020 16:50:14

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
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)	29 Sep 2020 10:47:14
User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral FEMUR. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:46:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone operation, LLT: Bone operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:22:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 08:22:33
Data point term sent to Coder	System	11 Aug 2020 23:09:50
User entered 'Femur Lengthening Surgery'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1997'	Etza Peters (b) (4)	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:20:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 23:20:53
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:20:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:08:56
User entered empty.	System	11 Aug 2020 23:08:56
	Etza Peters (b) (4)	11 Aug 2020 23:08:56
	(b) (4)	

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1997'	Etza Peters (b) (4)	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1997'	System	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1997'	System	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1997'	System	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1997'	System	11 Aug 2020 23:08:56

US3532002

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 02:49:05
User coded data point as SOC: Eye disorders, HLGT: Coder Import (b) (4) Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4)	20 Oct 2020 16:48:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 16:48:48
Data point term sent to Coder	System	20 Oct 2020 16:47:27
Coding entries removed.	Etza Peters (b) (4)	20 Oct 2020 16:46:28
User entered 'Bilateral CATARACTS' reason for change: Data Entry Error	(b) (4)	
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Bilateral' (Site from DM).	Etza Peters (b) (4)	20 Oct 2020 16:46:28
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Bilateral' (Site from DM).	Etza Peters (b) (4)	20 Oct 2020 16:46:19
User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:45:17
User coded data point as SOC: Eye disorders, HLGT: Coder Import (b) (4) Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	(b) (4)	11 Aug 2020 23:11:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 23:11:19

US3532002

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Aug 2020 23:10:53
User entered 'CATaRACTS' reason for change:	Etza Peters (b) (4)	11 Aug 2020 23:10:25
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 23:09:51
User entered 'Cateracts'	Etza Peters (b) (4)	11 Aug 2020 23:09:39
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 2018'	Etza Peters (b) (4)	11 Aug 2020 23:09:39

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:09:39

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:21:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 23:21:05
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:21:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:09:39
User entered empty.	System	11 Aug 2020 23:09:39
	Etza Peters (b) (4)	11 Aug 2020 23:09:39
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un Sep 2018'	Etza Peters (b) (4)	11 Aug 2020 23:09:39

US3532002

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:09:39

US3532002

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 2018'	System	11 Aug 2020 23:09:39

US3532002

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2018'	System	11 Aug 2020 23:09:39

US3532002

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Sep 2018'	System	11 Aug 2020 23:09:39

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2018'	System	11 Aug 2020 23:09:39

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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)	24 Oct 2020 23:50:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Oct 2020 23:50:41
User closed query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:42:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 10:16:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 10:16:34
Data point term sent to Coder	System	20 Oct 2020 16:47:28
Query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Updated' (Site from DM).	Etza Peters (b) (4)	20 Oct 2020 16:47:16
Coding entries removed.	Etza Peters (b) (4)	20 Oct 2020 16:47:10
User entered 'Bilateral CATARACT SURGERIES' reason for change: Data Entry Error	Etza Peters (b) (4)	20 Oct 2020 16:47:10
User opened query 'Per DM CLR: Please review and reflect if this involves the Right, Left or Bilateral EYES. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:45:04

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Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
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)	11 Aug 2020 23:13:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 23:13:20
Data point term sent to Coder	System	11 Aug 2020 23:12:55
User entered 'Cataract Surgery'	Etza Peters (b) (4)	11 Aug 2020 23:12:54
	(b) (4)	

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Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un Sep 2018'	Etza Peters (b) (4)	11 Aug 2020 23:12:54

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:12:54

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:21:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 23:21:12
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:21:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:12:54
User entered empty.	System	11 Aug 2020 23:12:54
	Etza Peters (b) (4)	11 Aug 2020 23:12:54
	(b) (4)	

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un Sep 2018'	Etza Peters (b) (4)	11 Aug 2020 23:12:54

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:12:54

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Sep 2018'	System	11 Aug 2020 23:12:54

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2018'	System	11 Aug 2020 23:12:54

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Sep 2018'	System	11 Aug 2020 23:12:54

US3532002

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2018'	System	11 Aug 2020 23:12:54

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 23:19:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 23:19:15
Data point term sent to Coder	System	11 Aug 2020 23:18:04
Coding entries removed.	Etza Peters (b) (4)	11 Aug 2020 23:17:16
User entered 'Hypothyroidism' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:17:16
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)	11 Aug 2020 23:13:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 23:13:20
Data point term sent to Coder	System	11 Aug 2020 23:11:54
User entered 'Cataract Surgery'	Etza Peters (b) (4)	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty; reason for change Data Entry Error	Etza Peters (b) (4)	01 Sep 2020 18:57:45
User entered 'un Sep 2018'	Etza Peters (b) (4)	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	01 Sep 2020 18:57:45
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	01 Sep 2020 18:57:34
User entered '1' reason for change: Data Entry Error	Etza Peters (b) (4)	01 Sep 2020 18:57:34
User entered '0'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:17:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 23:17:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:17:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Aug 2020 23:11:18
User entered empty.	System	11 Aug 2020 23:11:18
	Etza Peters (b) (4)	11 Aug 2020 23:11:18
	(b) (4)	

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty; reason for change Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:17:16
User entered 'un Sep 2018'	Etza Peters (b) (4)	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	01 Sep 2020 18:57:45
User entered 'Sep 2018'	System	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	01 Sep 2020 18:57:45
User entered '2018'	System	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 23:17:16
User entered 'Sep 2018'	System	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Aug 2020 23:17:16
User entered '2018'	System	11 Aug 2020 23:11:18

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 23:43:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 23:43:47
Data point term sent to Coder	System	22 Sep 2020 22:12:29
Coding entries removed.	Etza Peters (b) (4)	22 Sep 2020 22:11:42
User entered 'Degenerative Disk Disease of Back' reason for change: Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 22:11:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 18:58:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 18:58:51
Data point term sent to Coder	System	01 Sep 2020 18:58:12
User entered 'Back pain'	Etza Peters (b) (4)	01 Sep 2020 18:57:12

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'UN Nov 2019' reason for change:	(b) (4)	
Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 22:11:42
User entered empty.	(b) (4)	
	Etza Peters (b) (4)	01 Sep 2020 18:57:12
	(b) (4)	

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	22 Sep 2020 22:11:50
User entered '0' reason for change: Data Entry Error	System	22 Sep 2020 22:11:50
User entered '0' reason for change: Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 22:11:50
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	22 Sep 2020 22:11:42
User entered '1'	System	22 Sep 2020 22:11:42
	Etza Peters (b) (4)	01 Sep 2020 18:57:12
	(b) (4)	

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	01 Sep 2020 18:57:12

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 18:57:12

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 18:57:12

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Nov 2019'	System	22 Sep 2020 22:11:42
User entered empty.	System	01 Sep 2020 18:57:12

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2019'	System	22 Sep 2020 22:11:42
User entered empty.	System	01 Sep 2020 18:57:12

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	01 Sep 2020 18:57:12

US3532002

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	01 Sep 2020 18:57:12

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Cartilage injury, LLT: Cartilage tear in knee - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 19:25:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 19:25:02
Data point term sent to Coder	System	26 Oct 2020 18:21:24
User entered 'Torn Cartilage in Right Knee'	Etza Peters (b) (4)	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'I'	Etza Peters (b) (4)	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 1984'	Etza Peters (b) (4)	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1984'	System	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1984'	System	26 Oct 2020 18:21:18

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 17:07:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 17:07:48
Data point term sent to Coder	System	10 Dec 2020 17:07:21
User entered 'Rosacea'	Etza Peters (b) (4)	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un UNK 2010'	Etza Peters (b) (4)	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 2010'	System	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '2010'	System	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	10 Dec 2020 17:07:09

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:14:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 21:51:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 21:51:41
Data point term sent to Coder	System	09 Mar 2021 21:50:55
User entered 'Gout'	Teresa Ball (b) (4)	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:14:23
User entered 'UN UNK 1980'	Teresa Ball (b) (4)	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:14:23
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:14:23
User entered 'Yes (Y)'	Teresa Ball (b) (4)	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:14:23
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	27 Mar 2021 09:14:23
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'Jan 1980'	System	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '1980'	System	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	09 Mar 2021 21:50:54

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Aug 2020'	Etza Peters (b) (4)	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '15:11'	Etza Peters (b) (4)	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '11 Aug 2020 15:11'	System	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '174' cm	(b) (4) Etza Peters (b) (4)	11 Aug 2020 22:46:16
DataPoint set to visible.	(b) (4) System	11 Aug 2020 22:06:44

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '85.5' kg	(b) (4) Etza Peters (b) (4)	11 Aug 2020 22:46:16
DataPoint set to visible.	(b) (4) System	11 Aug 2020 22:06:44

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
Amendment Manager: User entered '28.24019'	System	16 Sep 2020 23:52:16
User entered '28.2'	System	11 Aug 2020 22:46:16
DataPoint set to visible.	System	11 Aug 2020 22:06:44

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'kg/m2'	System	11 Aug 2020 22:46:16
DataPoint set to visible.	System	11 Aug 2020 22:06:44

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Aug 2020 09:27:47
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'DONE' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	26 Aug 2020 01:38:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4) (b) (4)	26 Aug 2020 01:38:48
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 09:36:33
User entered '98.9' F	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 01:38:48
User entered 'Oral (Oral)'	Etza Peters (b) (4)	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 01:38:48
User entered '80'	Laila Hussaini (b) (4)	11 Aug 2020 22:46:16
	(b) (4)	

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'bpm'	System	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 01:38:48
User entered '12'	Laila Hussaini (b) (4)	11 Aug 2020 22:46:16
	Etza Peters (b) (4)	
	(b) (4)	

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'breaths/min'	System	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 01:38:48
User entered '139'	Laila Hussaini (b) (4)	11 Aug 2020 22:46:16
	Etza Peters (b) (4)	
	(b) (4)	

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'mmHg'	System	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 01:38:48
User entered '89'	Laila Hussaini (b) (4)	11 Aug 2020 22:46:16
	(b) (4)	

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'mmHg'	System	11 Aug 2020 22:46:16

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54

US3532002

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54

US3532002

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:43:30

US3532002

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:36:34
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 12:21:11
User entered '11 Aug 2020'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:43:30

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

[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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

[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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

[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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Engineer-performs site inspections 3X/week'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

[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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'I'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:06:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:27:29

US3532002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 19:35:09

US3532002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '11 Aug 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 19:35:09

US3532002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Clinic (Clinic)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 19:35:09

US3532002

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'VISIT1'	System	11 Aug 2020 19:35:09

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 20:44:29

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:40:03
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:40:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 20:44:29
User entered '143706' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 20:44:29

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 20:44:29

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 21:26:40

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 21:26:40

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 21:26:40

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 21:26:40

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 21:26:40

US3532002

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:06:59

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'No (N)'	(b) (4) Etza Peters (b) (4)	24 Sep 2020 18:08:02
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:17:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:35:35

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Aug 2020 10:17:55
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM).	Laila Hussaini (b) (4)	26 Aug 2020 01:40:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 01:40:15
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 01:53:01
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 01:40:22
User entered empty.	Laila Hussaini (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Aug 2020 10:17:55
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM).	Laila Hussaini (b) (4)	26 Aug 2020 01:40:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 01:40:15
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 01:53:01
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 01:40:22
User entered empty.	Laila Hussaini (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User accepted default value 'Pre-Dose (PREDOSE)'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:44:20
User entered '11 Aug 2020' reason for change: Data Entry Error	System	11 Aug 2020 23:44:20
User opened query 'Data is required. Please provide.' (Site from System).	Etza Peters (b) (4)	11 Aug 2020 22:26:58
User entered empty.	(b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:44:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:44:20
User entered '15:11' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:44:20
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 22:26:58
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '11 Aug 2020 15:11'	System	11 Aug 2020 23:44:20
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:44:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:44:20
User entered '98.9' F reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:44:20
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 22:26:58
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:45:11
User entered 'Oral (Oral)' reason for change: Data Entry Error	System	11 Aug 2020 23:45:11
User opened query 'Data is required. Please provide.' (Site from System).	Etza Peters (b) (4)	11 Aug 2020 22:26:58
User entered empty.	(b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:45:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:45:11
User entered '80' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:45:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 22:26:58
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'bpm'	System	11 Aug 2020 23:45:11
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:45:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:45:11
User entered '12' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:45:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 22:26:58
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'breaths/min'	System	11 Aug 2020 23:45:11
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:45:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:45:11
User entered '139' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:45:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 22:26:58
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	11 Aug 2020 23:45:11
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:45:11
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:45:11
User entered '89' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:45:11
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 22:26:58
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	11 Aug 2020 23:45:11
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Aug 2020 10:17:55
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'DONE' (Site from DM).	Laila Hussaini (b) (4)	26 Aug 2020 01:40:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Laila Hussaini (b) (4)	26 Aug 2020 01:40:15
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 01:53:01
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:06:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Aug 2020 01:40:22
User entered empty.	Laila Hussaini (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User accepted default value 'Post-Dose (POSTDOSE)'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:26:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
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	11 Aug 2020 23:45:48
User entered 'Yes (Y)' reason for change: Data Entry Error	System	11 Aug 2020 23:45:48
User opened query 'Data is required. Please complete.' (Site from System).	Etza Peters (b) (4)	11 Aug 2020 22:26:58
User entered empty.	System	11 Aug 2020 22:26:58
	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '11 Aug 2020' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 23:45:48
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 01:49:43
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	12 Aug 2020 12:39:57
User entered '17:51' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	12 Aug 2020 12:39:57
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol 30 minutes or greater' (Site from System).	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:47:03
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	11 Aug 2020 23:45:48
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	11 Aug 2020 23:45:48
User entered '14:51' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:45:48
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:26:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '11 Aug 2020 17:51'	System	12 Aug 2020 12:39:57
User entered '11 Aug 2020 14:51'	System	11 Aug 2020 23:45:48
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	12 Aug 2020 12:35:51
User entered '98.4' F reason for change: Data Entry Error	System	12 Aug 2020 12:35:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Etza Peters (b) (4)	12 Aug 2020 12:35:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:46:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:46:22
User entered '98.4' (non-conformant).	System	11 Aug 2020 23:46:22
User opened query 'Data is required. Please provide.' (Site from System).	Etza Peters (b) (4)	11 Aug 2020 23:45:48
User entered empty.	System	11 Aug 2020 22:26:58
	Etza Peters (b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:46:22
User entered 'Oral (Oral)' reason for change: Data Entry Error	System	11 Aug 2020 23:46:22
User opened query 'Data is required. Please provide.' (Site from System).	Etza Peters (b) (4)	11 Aug 2020 23:45:48
User entered empty.	(b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:46:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:46:22
User entered '71' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:46:22
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:45:48
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'bpm'	System	11 Aug 2020 23:46:22
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:46:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:46:22
User entered '12' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:46:22
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:45:48
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'breaths/min'	System	11 Aug 2020 23:46:22
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Re-Query : Per query response, please indicate if CS/NCS and report as AE, if appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 14:12:08
Query 'Re-Query : Per query response, please indicate if CS/NCS and report as AE, if appropriate. Thank you.' answered with 'NCS, Not related: Due to underlying hypertension and due for evening meds' (Site from DM).	Etza Peters (b) (4) (b) (4)	12 Aug 2020 12:42:07
User opened query 'Re-Query : Per query response, please indicate if CS/NCS and report as AE, if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Aug 2020 11:01:34
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:00:50
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject due to take his evening blood pressure medicaion' (Site from System).	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:48:24
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 23:46:22
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 23:46:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:46:22
User entered '165' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:46:22
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 23:45:48
User entered empty.	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:26:58

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	11 Aug 2020 23:46:22
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:46:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Aug 2020 23:46:22
User entered '95' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:46:22
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Aug 2020 23:45:48
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 22:26:58
	(b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	11 Aug 2020 23:46:22
User entered empty.	System	11 Aug 2020 22:26:58

US3532002

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:11:05

US3532002

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '11 Aug 2020'	Etza Peters (b) (4)	11 Aug 2020 22:11:05

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Aug 2020'	Etza Peters (b) (4)	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '17:21'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '11 Aug 2020 17:21'	System	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Left Arm (LEFT ARM)'	Etza Peters (b) (4)	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'ONCE'	System	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 22:10:10

US3532002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4)	11 Aug 2020 22:10:40

US3532002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '11 Aug 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:10:40

US3532002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '16:49'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:10:40

US3532002

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '11 Aug 2020 16:49'	System	11 Aug 2020 22:10:40

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:06:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Aug 2020'	Etza Peters (b) (4)	11 Aug 2020 22:08:48

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:08:48

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:08:48

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:59

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '16:35'	Etza Peters (b) (4)	11 Aug 2020 22:08:48

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '11 Aug 2020 16:35'	System	11 Aug 2020 22:08:48

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:08:48

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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	11 Aug 2020 22:08:57
User entered 'No (N)' reason for change: Data Entry Error	System	11 Aug 2020 22:08:57
User opened query 'Data is required. Please complete.' (Site from System).	Etza Peters (b) (4)	11 Aug 2020 22:08:57
User entered empty.	(b) (4)	
	System	11 Aug 2020 22:08:48
	Etza Peters (b) (4)	11 Aug 2020 22:08:48
	(b) (4)	

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 22:08:48

US3532002

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered empty.	System	11 Aug 2020 22:08:48

US3532002

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 22:10:48

US3532002

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	11 Aug 2020 22:10:48

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'eb4a6fdb-d1e8-4261-9f6b-cad254d705e4'	System	11 Aug 2020 22:17:26
User entered 'Yes (Y)'	System	11 Aug 2020 22:17:26

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'eb4a6fdb-d1e8-4261-9f6b-cad254d705e4'	System	11 Aug 2020 22:17:26
User entered '98.4'	System	11 Aug 2020 22:17:26

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'eb4a6fdb-d1e8-4261-9f6b-cad254d705e4'	System	11 Aug 2020 22:17:26
User entered 'No (N)'	System	11 Aug 2020 22:17:26

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:23', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'eb4a6fdb-d1e8-4261-9f6b-cad254d705e4'	System	11 Aug 2020 22:17:26
User entered '11 Aug 2020 18:17'	System	11 Aug 2020 22:17:26

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 17:41'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 20:11'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:20:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0d5830c-edf9-460e-9a92-ccacbeefc355'	System	12 Aug 2020 01:29:04
User entered 'Yes (Y)'	System	12 Aug 2020 01:29:04

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:28:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0d5830c-edf9-460e-9a92-ccacbeefc355'	System	12 Aug 2020 01:29:04
User entered '97.6'	System	12 Aug 2020 01:29:04

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:28:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0d5830c-edf9-460e-9a92-ccacbeefc355'	System	12 Aug 2020 01:29:04
User entered 'No (N)'	System	12 Aug 2020 01:29:04

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:29:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0d5830c-edf9-460e-9a92-ccacbeefc355'	System	12 Aug 2020 01:29:04
User entered '11 Aug 2020 21:29'	System	12 Aug 2020 01:29:04

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 21:06'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 2'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:18:27', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1c181a4-feddd-499f-83db-04ee64f657c5'	System	12 Aug 2020 16:18:49
User entered 'Yes (Y)'	System	12 Aug 2020 16:18:49

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:18:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1c181a4-fedd-499f-83db-04ee64f657c5'	System	12 Aug 2020 16:18:49
User entered '97.2'	System	12 Aug 2020 16:18:49

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:18:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1c181a4-fedd-499f-83db-04ee64f657c5'	System	12 Aug 2020 16:18:49
User entered 'No (N)'	System	12 Aug 2020 16:18:49

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:18:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1c181a4-fedd-499f-83db-04ee64f657c5'	System	12 Aug 2020 16:18:49
User entered '12 Aug 2020 12:18'	System	12 Aug 2020 16:18:49

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 3'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:34:58', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'beeadd3-3a28-45ab-b2a2-4ee9c6cd24f3'	System	13 Aug 2020 20:35:34
User entered 'Yes (Y)'	System	13 Aug 2020 20:35:34

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:20', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'beeadd3-3a28-45ab-b2a2-4ee9c6cd24f3'	System	13 Aug 2020 20:35:34
User entered '97.8'	System	13 Aug 2020 20:35:34

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'beeadd3-3a28-45ab-b2a2-4ee9c6cd24f3'	System	13 Aug 2020 20:35:34
User entered 'No (N)'	System	13 Aug 2020 20:35:34

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'beeadd3-3a28-45ab-b2a2-4ee9c6cd24f3'	System	13 Aug 2020 20:35:34
User entered '13 Aug 2020 16:35'	System	13 Aug 2020 20:35:34

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 4'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:20:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cf1107e1-d38d-4659-8bf9-9d070c456b56'	System	14 Aug 2020 22:21:19
User entered 'Yes (Y)'	System	14 Aug 2020 22:21:19

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cf1107e1-d38d-4659-8bf9-9d070c456b56'	System	14 Aug 2020 22:21:19
User entered '98.0'	System	14 Aug 2020 22:21:19

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cf1107e1-d38d-4659-8bf9-9d070c456b56'	System	14 Aug 2020 22:21:19
User entered 'No (N)'	System	14 Aug 2020 22:21:19

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cf1107e1-d38d-4659-8bf9-9d070c456b56'	System	14 Aug 2020 22:21:19
User entered '14 Aug 2020 18:21'	System	14 Aug 2020 22:21:19

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 5'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:09:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f993e0ba-0525-4aa6-8678-c85ee3d9fbc2'	System	15 Aug 2020 22:10:49
User entered 'Yes (Y)'	System	15 Aug 2020 22:10:49

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:10:36', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f993e0ba-0525-4aa6-8678-c85ee3d9fbc2'	System	15 Aug 2020 22:10:49
User entered '98.1'	System	15 Aug 2020 22:10:49

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:10:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f993e0ba-0525-4aa6-8678-c85ee3d9fbc2'	System	15 Aug 2020 22:10:49
User entered 'No (N)'	System	15 Aug 2020 22:10:49

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:10:46', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f993e0ba-0525-4aa6-8678-c85ee3d9fbc2'	System	15 Aug 2020 22:10:49
User entered '15 Aug 2020 18:10'	System	15 Aug 2020 22:10:49

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 6'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:01', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e285af8-30a5-475d-a292-0182b1bca11d'	System	16 Aug 2020 23:41:22
User entered 'Yes (Y)'	System	16 Aug 2020 23:41:22

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e285af8-30a5-475d-a292-0182b1bca11d'	System	16 Aug 2020 23:41:22
User entered '98.1'	System	16 Aug 2020 23:41:22

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e285af8-30a5-475d-a292-0182b1bca11d'	System	16 Aug 2020 23:41:22
User entered 'No (N)'	System	16 Aug 2020 23:41:22

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e285af8-30a5-475d-a292-0182b1bca11d'	System	16 Aug 2020 23:41:22
User entered '16 Aug 2020 19:41'	System	16 Aug 2020 23:41:22

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 7'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:08', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4fa5a3d-7484-4575-b9ea-b1fde0c6c63d'	System	17 Aug 2020 21:32:25
User entered 'Yes (Y)'	System	17 Aug 2020 21:32:25

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4fa5a3d-7484-4575-b9ea-b1fde0c6c63d'	System	17 Aug 2020 21:32:25
User entered '97.8'	System	17 Aug 2020 21:32:25

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:18', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4fa5a3d-7484-4575-b9ea-b1fde0c6c63d'	System	17 Aug 2020 21:32:25
User entered 'No (N)'	System	17 Aug 2020 21:32:25

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4fa5a3d-7484-4575-b9ea-b1fde0c6c63d'	System	17 Aug 2020 21:32:25
User entered '17 Aug 2020 17:32'	System	17 Aug 2020 21:32:25

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:52', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601'	System	11 Aug 2020 22:18:23
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 22:18:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:17:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601'	System	11 Aug 2020 22:18:23
User entered 'No (N)'	System	11 Aug 2020 22:18:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:18:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601'	System	11 Aug 2020 22:18:23
User entered 'No (N)'	System	11 Aug 2020 22:18:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:18:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601'	System	11 Aug 2020 22:18:23
User entered 'None (1)'	System	11 Aug 2020 22:18:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:18:20', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '88a3e73c-114f-4570-a49c-f1c65871d601'	System	11 Aug 2020 22:18:23
User entered '11 Aug 2020 18:18'	System	11 Aug 2020 22:18:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 17:41'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 20:11'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:29:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8'	System	12 Aug 2020 01:32:40
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 01:32:40

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:29:28', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8'	System	12 Aug 2020 01:32:40
User entered 'No (N)'	System	12 Aug 2020 01:32:40

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:29:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8'	System	12 Aug 2020 01:32:40
User entered 'Yes (Y)'	System	12 Aug 2020 01:32:40

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Comment added 'Per conversation with subject he believed the measurements were in cm not mm and therefore entered 2. The correct recording should be 20 mm.'	Laila Hussaini (b) (4) (b) (4)	14 Aug 2020 01:33:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8'	System	12 Aug 2020 01:32:40
User entered '2'	System	12 Aug 2020 01:32:40

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8'	System	12 Aug 2020 01:32:40
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 01:32:40

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:37', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5acc9fa2-4d40-4293-a15d-6b4a77c482a8'	System	12 Aug 2020 01:32:40
User entered '11 Aug 2020 21:32'	System	12 Aug 2020 01:32:40

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 21:06'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 2'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:19:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50'	System	12 Aug 2020 16:20:57
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 16:20:57

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:19:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50'	System	12 Aug 2020 16:20:57
User entered 'No (N)'	System	12 Aug 2020 16:20:57

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:19:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50'	System	12 Aug 2020 16:20:57
User entered 'Yes (Y)'	System	12 Aug 2020 16:20:57

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:20:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50'	System	12 Aug 2020 16:20:57
User entered '30'	System	12 Aug 2020 16:20:57

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:20:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50'	System	12 Aug 2020 16:20:57
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 16:20:57

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:20:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '860ec768-d10c-4a46-88e1-064bfa496b50'	System	12 Aug 2020 16:20:57
User entered '12 Aug 2020 12:20'	System	12 Aug 2020 16:20:57

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 3'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6'	System	13 Aug 2020 20:36:23
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 20:36:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:46', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6'	System	13 Aug 2020 20:36:23
User entered 'No (N)'	System	13 Aug 2020 20:36:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:35:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6'	System	13 Aug 2020 20:36:23
User entered 'Yes (Y)'	System	13 Aug 2020 20:36:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6'	System	13 Aug 2020 20:36:23
User entered '25'	System	13 Aug 2020 20:36:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6'	System	13 Aug 2020 20:36:23
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 20:36:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e83b742f-6575-4958-93bf-584276e120c6'	System	13 Aug 2020 20:36:23
User entered '13 Aug 2020 16:36'	System	13 Aug 2020 20:36:23

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 4'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:36', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b'	System	14 Aug 2020 22:22:03
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 22:22:03

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b'	System	14 Aug 2020 22:22:03
User entered 'No (N)'	System	14 Aug 2020 22:22:03

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:43', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b'	System	14 Aug 2020 22:22:03
User entered 'No (N)'	System	14 Aug 2020 22:22:03

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:21:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b'	System	14 Aug 2020 22:22:03
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 22:22:03

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '76056529-4d46-48dd-8e90-71f5a300263b'	System	14 Aug 2020 22:22:03
User entered '14 Aug 2020 18:22'	System	14 Aug 2020 22:22:03

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 5'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:11:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca'	System	15 Aug 2020 22:11:59
User entered 'None (1)'	System	15 Aug 2020 22:11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:11:41', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca'	System	15 Aug 2020 22:11:59
User entered 'No (N)'	System	15 Aug 2020 22:11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:11:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca'	System	15 Aug 2020 22:11:59
User entered 'No (N)'	System	15 Aug 2020 22:11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:11:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca'	System	15 Aug 2020 22:11:59
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 22:11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:11:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '21b37c0d-85dd-4beb-9654-3fc6270db9ca'	System	15 Aug 2020 22:11:59
User entered '15 Aug 2020 18:11'	System	15 Aug 2020 22:11:59

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 6'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28'	System	16 Aug 2020 23:42:10
User entered 'None (1)'	System	16 Aug 2020 23:42:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28'	System	16 Aug 2020 23:42:10
User entered 'No (N)'	System	16 Aug 2020 23:42:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:41:41', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28'	System	16 Aug 2020 23:42:10
User entered 'No (N)'	System	16 Aug 2020 23:42:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28'	System	16 Aug 2020 23:42:10
User entered 'None (1)'	System	16 Aug 2020 23:42:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c146430-45d5-41da-806b-f1f9714eca28'	System	16 Aug 2020 23:42:10
User entered '16 Aug 2020 19:42'	System	16 Aug 2020 23:42:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 7'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:27', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655'	System	17 Aug 2020 21:33:10
User entered 'None (1)'	System	17 Aug 2020 21:33:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655'	System	17 Aug 2020 21:33:10
User entered 'No (N)'	System	17 Aug 2020 21:33:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:32:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655'	System	17 Aug 2020 21:33:10
User entered 'No (N)'	System	17 Aug 2020 21:33:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655'	System	17 Aug 2020 21:33:10
User entered 'None (1)'	System	17 Aug 2020 21:33:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '4ab55426-bab1-4807-98d1-d44ad214e655'	System	17 Aug 2020 21:33:10
User entered '17 Aug 2020 17:33'	System	17 Aug 2020 21:33:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:18:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc'	System	11 Aug 2020 22:20:02
User entered 'None (0)'	System	11 Aug 2020 22:20:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc'	System	11 Aug 2020 22:20:02
User entered 'None (0)'	System	11 Aug 2020 22:20:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc'	System	11 Aug 2020 22:20:02
User entered 'None (0)'	System	11 Aug 2020 22:20:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc'	System	11 Aug 2020 22:20:02
User entered 'None (0)'	System	11 Aug 2020 22:20:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:36', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc'	System	11 Aug 2020 22:20:02
User entered 'None (0)'	System	11 Aug 2020 22:20:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc'	System	11 Aug 2020 22:20:02
User entered 'None (0)'	System	11 Aug 2020 22:20:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc'	System	11 Aug 2020 22:20:02
User entered 'No (N)'	System	11 Aug 2020 22:20:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T18:19:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a594cd0c-fc67-4456-8042-aea8f7565dbc'	System	11 Aug 2020 22:20:02
User entered '11 Aug 2020 18:19'	System	11 Aug 2020 22:20:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 17:41'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 20:11'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65'	System	12 Aug 2020 01:33:36
User entered 'No interference with activity (1)'	System	12 Aug 2020 01:33:36

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:32:59', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65'	System	12 Aug 2020 01:33:36
User entered 'None (0)'	System	12 Aug 2020 01:33:36

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65'	System	12 Aug 2020 01:33:36
User entered 'None (0)'	System	12 Aug 2020 01:33:36

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65'	System	12 Aug 2020 01:33:36
User entered 'None (0)'	System	12 Aug 2020 01:33:36

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65'	System	12 Aug 2020 01:33:36
User entered 'None (0)'	System	12 Aug 2020 01:33:36

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:18', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65'	System	12 Aug 2020 01:33:36
User entered 'None (0)'	System	12 Aug 2020 01:33:36

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:28', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65'	System	12 Aug 2020 01:33:36
User entered 'No (N)'	System	12 Aug 2020 01:33:36

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-11T21:33:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ed7deb85-9fe8-4ff4-b513-c6532d06ec65'	System	12 Aug 2020 01:33:36
User entered '11 Aug 2020 21:33'	System	12 Aug 2020 01:33:36

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '11 Aug 2020 21:06'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 2'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd'	System	12 Aug 2020 16:22:14
User entered 'No interference with activity (1)'	System	12 Aug 2020 16:22:14

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd'	System	12 Aug 2020 16:22:14
User entered 'No interference with activity (1)'	System	12 Aug 2020 16:22:14

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' User entered 'None (0)'	System	12 Aug 2020 16:22:14
	System	12 Aug 2020 16:22:14

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd' User entered 'None (0)'	System	12 Aug 2020 16:22:14
	System	12 Aug 2020 16:22:14

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd'	System	12 Aug 2020 16:22:14
User entered 'None (0)'	System	12 Aug 2020 16:22:14

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:21:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd'	System	12 Aug 2020 16:22:14
User entered 'None (0)'	System	12 Aug 2020 16:22:14

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

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)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:22:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd'	System	12 Aug 2020 16:22:14
User entered 'No (N)'	System	12 Aug 2020 16:22:14

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-12T12:22:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a97626d3-add4-4915-9a2e-5b685a4472bd'	System	12 Aug 2020 16:22:14
User entered '12 Aug 2020 12:22'	System	12 Aug 2020 16:22:14

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 3'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876'	System	13 Aug 2020 20:37:05
User entered 'No interference with activity (1)'	System	13 Aug 2020 20:37:05

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:32', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876'	System	13 Aug 2020 20:37:05
User entered 'None (0)'	System	13 Aug 2020 20:37:05

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876'	System	13 Aug 2020 20:37:05
User entered 'None (0)'	System	13 Aug 2020 20:37:05

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876'	System	13 Aug 2020 20:37:05
User entered 'None (0)'	System	13 Aug 2020 20:37:05

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876'	System	13 Aug 2020 20:37:05
User entered 'None (0)'	System	13 Aug 2020 20:37:05

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876'	System	13 Aug 2020 20:37:05
User entered 'None (0)'	System	13 Aug 2020 20:37:05

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

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)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:36:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876'	System	13 Aug 2020 20:37:05
User entered 'No (N)'	System	13 Aug 2020 20:37:05

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-13T16:37:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '422e4635-fd9f-4de5-9e75-3bce4bee6876'	System	13 Aug 2020 20:37:05
User entered '13 Aug 2020 16:37'	System	13 Aug 2020 20:37:05

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 4'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11'	System	14 Aug 2020 22:23:02
User entered 'None (0)'	System	14 Aug 2020 22:23:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11'	System	14 Aug 2020 22:23:02
User entered 'None (0)'	System	14 Aug 2020 22:23:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11'	System	14 Aug 2020 22:23:02
User entered 'None (0)'	System	14 Aug 2020 22:23:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:43', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11'	System	14 Aug 2020 22:23:02
User entered 'None (0)'	System	14 Aug 2020 22:23:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11'	System	14 Aug 2020 22:23:02
User entered 'None (0)'	System	14 Aug 2020 22:23:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11'	System	14 Aug 2020 22:23:02
User entered 'None (0)'	System	14 Aug 2020 22:23:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

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)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:22:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11'	System	14 Aug 2020 22:23:02
User entered 'No (N)'	System	14 Aug 2020 22:23:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-14T18:23:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '9bd44d2b-da85-4d90-a8af-91129639ab11'	System	14 Aug 2020 22:23:02
User entered '14 Aug 2020 18:23'	System	14 Aug 2020 22:23:02

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 5'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058'	System	15 Aug 2020 22:12:26
User entered 'None (0)'	System	15 Aug 2020 22:12:26

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058'	System	15 Aug 2020 22:12:26
User entered 'None (0)'	System	15 Aug 2020 22:12:26

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058'	System	15 Aug 2020 22:12:26
User entered 'None (0)'	System	15 Aug 2020 22:12:26

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058'	System	15 Aug 2020 22:12:26
User entered 'None (0)'	System	15 Aug 2020 22:12:26

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058'	System	15 Aug 2020 22:12:26
User entered 'None (0)'	System	15 Aug 2020 22:12:26

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058'	System	15 Aug 2020 22:12:26
User entered 'None (0)'	System	15 Aug 2020 22:12:26

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

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)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058'	System	15 Aug 2020 22:12:26
User entered 'No (N)'	System	15 Aug 2020 22:12:26

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-15T18:12:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a358e359-43d3-4280-bdd1-825442a0e058'	System	15 Aug 2020 22:12:26
User entered '15 Aug 2020 18:12'	System	15 Aug 2020 22:12:26

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 6'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:10', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae'	System	16 Aug 2020 23:43:01
User entered 'None (0)'	System	16 Aug 2020 23:43:01

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:15', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae'	System	16 Aug 2020 23:43:01
User entered 'None (0)'	System	16 Aug 2020 23:43:01

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae'	System	16 Aug 2020 23:43:01
User entered 'None (0)'	System	16 Aug 2020 23:43:01

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae'	System	16 Aug 2020 23:43:01
User entered 'None (0)'	System	16 Aug 2020 23:43:01

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae'	System	16 Aug 2020 23:43:01
User entered 'None (0)'	System	16 Aug 2020 23:43:01

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:28', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae'	System	16 Aug 2020 23:43:01
User entered 'None (0)'	System	16 Aug 2020 23:43:01

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

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)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae'	System	16 Aug 2020 23:43:01
User entered 'No (N)'	System	16 Aug 2020 23:43:01

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-16T19:42:58', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c0dc92c-ba29-4828-b752-99225f4735ae'	System	16 Aug 2020 23:43:01
User entered '16 Aug 2020 19:42'	System	16 Aug 2020 23:43:01

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 7'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3'	System	17 Aug 2020 21:33:48
User entered 'None (0)'	System	17 Aug 2020 21:33:48

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3'	System	17 Aug 2020 21:33:48
User entered 'None (0)'	System	17 Aug 2020 21:33:48

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3'	System	17 Aug 2020 21:33:48
User entered 'None (0)'	System	17 Aug 2020 21:33:48

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:23', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3'	System	17 Aug 2020 21:33:48
User entered 'None (0)'	System	17 Aug 2020 21:33:48

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3'	System	17 Aug 2020 21:33:48
User entered 'None (0)'	System	17 Aug 2020 21:33:48

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3'	System	17 Aug 2020 21:33:48
User entered 'None (0)'	System	17 Aug 2020 21:33:48

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

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)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3'	System	17 Aug 2020 21:33:48
User entered 'No (N)'	System	17 Aug 2020 21:33:48

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-08-17T17:33:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a05cc05b-8b2a-4380-beab-7743edbfd1b3'	System	17 Aug 2020 21:33:48
User entered '17 Aug 2020 17:33'	System	17 Aug 2020 21:33:48

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 22:10:10

US3532002

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 20:47:37
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Cindy Lubbers (b) (4)	17 Aug 2020 22:39:45

US3532002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 01:54:21
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'In window' (Site from System).	Cindy Lubbers (b) (4) (b) (4)	17 Aug 2020 22:40:44
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	17 Aug 2020 22:39:45
User entered '17 Aug 2020'	Cindy Lubbers (b) (4) (b) (4)	17 Aug 2020 22:39:45

US3532002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	17 Aug 2020 22:39:45

US3532002

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Cindy Lubbers (b) (4) (b) (4)	17 Aug 2020 22:39:45

US3532002

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	(b) (4) Cindy Lubbers (b) (4) (b) (4)	17 Aug 2020 22:40:55

US3532002

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	17 Aug 2020 22:40:55

US3532002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	25 Aug 2020 23:05:56

US3532002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '25 Aug 2020'	Etza Peters (b) (4)	25 Aug 2020 23:05:56

US3532002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	Etza Peters (b) (4)	25 Aug 2020 23:05:56

US3532002

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	25 Aug 2020 23:05:56

US3532002

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	25 Aug 2020 23:10:58

US3532002

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	25 Aug 2020 23:10:58

US3532002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	01 Sep 2020 18:58:06

US3532002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Kathy Stephens (b) (4)	10 Nov 2020 23:40:55
User entered '1 Sep 2020'	(b) (4)	
	Etza Peters (b) (4)	01 Sep 2020 18:58:06
	(b) (4)	

US3532002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	Etza Peters (b) (4)	01 Sep 2020 18:58:06

US3532002

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	01 Sep 2020 18:58:06

US3532002

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	01 Sep 2020 19:00:44

US3532002

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	01 Sep 2020 19:00:44

US3532002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:21:11

US3532002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '8 Sep 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:21:11

US3532002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Clinic (Clinic)'	Etza Peters (b) (4)	08 Sep 2020 12:21:11

US3532002

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'VISIT2'	System	08 Sep 2020 12:21:11

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User accepted default value 'Pre-Dose (PREDOSE)'	Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '8 Sep 2020'	Etza Peters (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '07:40'	Etza Peters (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '8 Sep 2020 07:40'	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '98.5' F reason for change: Data Entry Error	System	08 Sep 2020 22:45:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Etza Peters (b) (4)	08 Sep 2020 22:45:55
User entered '98.5' (non-conformant).	(b) (4)	
	System	08 Sep 2020 12:24:03
	Etza Peters (b) (4)	08 Sep 2020 12:24:03
	(b) (4)	

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Oral (Oral)'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '64'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'bpm'	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '16'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'breaths/min'	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '114'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '75'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User accepted default value 'Post-Dose (POSTDOSE)'	Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
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	08 Sep 2020 13:29:25
User entered 'Yes (Y)' reason for change: Data Entry Error	System	08 Sep 2020 13:29:25
User opened query 'Data is required. Please complete.' (Site from System).	Etza Peters (b) (4)	08 Sep 2020 13:29:25
User entered empty.	(b) (4)	
	System	08 Sep 2020 12:24:03
	Etza Peters (b) (4)	08 Sep 2020 12:24:03
	(b) (4)	

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Sep 2020 13:29:37
User entered '8 Sep 2020' reason for change: Data Entry Error	System	08 Sep 2020 13:29:37
User opened query 'Data is required. Please provide.' (Site from System).	Etza Peters (b) (4)	08 Sep 2020 13:29:25
User entered empty.	(b) (4)	08 Sep 2020 13:29:25
	Etza Peters (b) (4)	08 Sep 2020 12:24:03
	(b) (4)	

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '09:12' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Sep 2020 13:29:25
User entered empty.	Etza Peters (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '8 Sep 2020 09:12'	System	08 Sep 2020 13:29:37
User entered empty.	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.2' F reason for change: Data Entry Error	System	08 Sep 2020 13:29:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Etza Peters (b) (4)	08 Sep 2020 13:29:37
User entered '97.2' (non-conformant).	(b) (4)	
User entered empty.	System	08 Sep 2020 13:29:25
	Etza Peters (b) (4)	08 Sep 2020 13:29:25
	(b) (4)	
	Etza Peters (b) (4)	08 Sep 2020 12:24:03
	(b) (4)	

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Sep 2020 13:29:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Sep 2020 13:29:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Sep 2020 13:29:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Sep 2020 13:29:37
User entered empty.	Etza Peters (b) (4)	08 Sep 2020 12:24:03
	(b) (4)	

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '61' reason for change: Data Entry Error	(b) (4)	
	Etza Peters (b) (4)	08 Sep 2020 13:29:25
User entered empty.	(b) (4)	
	Etza Peters (b) (4)	08 Sep 2020 12:24:03
	(b) (4)	

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'bpm'	System	08 Sep 2020 13:29:25
User entered empty.	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '16' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Sep 2020 13:29:25
User entered empty.	Etza Peters (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'breaths/min'	System	08 Sep 2020 13:29:25
User entered empty.	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '111' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Sep 2020 13:29:25
User entered empty.	Etza Peters (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	08 Sep 2020 13:29:25
User entered empty.	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '73' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Sep 2020 13:29:25
User entered empty.	Etza Peters (b) (4)	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	08 Sep 2020 13:29:25
User entered empty.	System	08 Sep 2020 12:24:03

US3532002

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	Etza Peters (b) (4)	08 Sep 2020 12:21:20

US3532002

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '8 Sep 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:21:20

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	08 Sep 2020 12:52:12
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	08 Sep 2020 12:52:12
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	08 Sep 2020 12:49:08
User entered 'Yes (Y)'	Etza Peters (b) (4)	08 Sep 2020 12:49:08
	(b) (4)	

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	Etza Peters (b) (4)	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '8 Sep 2020'	Etza Peters (b) (4)	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '08:40' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Sep 2020 12:52:12
User entered empty.	Etza Peters (b) (4)	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '8 Sep 2020 08:40'	System	08 Sep 2020 12:52:12
User entered empty.	System	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Left Arm (LEFT ARM)'	Etza Peters (b) (4)	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'ONCE'	System	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:06:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 12:49:08

US3532002

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4)	08 Sep 2020 12:24:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '8 Sep 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:24:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '08:07' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Sep 2020 12:25:41
User entered '07:51'	Etza Peters (b) (4)	08 Sep 2020 12:24:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '8 Sep 2020 08:07'	System	08 Sep 2020 12:25:41
User entered '8 Sep 2020 07:51'	System	08 Sep 2020 12:24:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:06:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '8 Sep 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	Etza Peters (b) (4)	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '07:51'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '8 Sep 2020 07:51'	System	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered empty.	System	08 Sep 2020 12:25:22

US3532002

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4)	08 Sep 2020 13:29:49

US3532002

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	08 Sep 2020 13:29:49

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:15:52', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f942c075-8fcb-4e44-9f2f-b96fafd0b1d8'	System	08 Sep 2020 13:16:15
User entered 'Yes (Y)'	System	08 Sep 2020 13:16:15

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:01', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f942c075-8fcb-4e44-9f2f-b96fafd0b1d8'	System	08 Sep 2020 13:16:15
User entered '97.2'	System	08 Sep 2020 13:16:15

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f942c075-8fcb-4e44-9f2f-b96fafd0b1d8'	System	08 Sep 2020 13:16:15
User entered 'No (N)'	System	08 Sep 2020 13:16:15

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f942c075-8fcb-4e44-9f2f-b96fafd0b1d8'	System	08 Sep 2020 13:16:15
User entered '08 Sep 2020 09:16'	System	08 Sep 2020 13:16:15

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 09:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 11:30'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:06:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b6c85710-c427-42a1-9d96-32c2e294f86d'	System	08 Sep 2020 23:06:33
User entered 'Yes (Y)'	System	08 Sep 2020 23:06:33

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:06:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b6c85710-c427-42a1-9d96-32c2e294f86d' User entered '97.6'	System	08 Sep 2020 23:06:33
	System	08 Sep 2020 23:06:33

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:06:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b6c85710-c427-42a1-9d96-32c2e294f86d'	System	08 Sep 2020 23:06:33
User entered 'No (N)'	System	08 Sep 2020 23:06:33

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:06:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b6c85710-c427-42a1-9d96-32c2e294f86d'	System	08 Sep 2020 23:06:33
User entered '08 Sep 2020 19:06'	System	08 Sep 2020 23:06:33

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 12:25'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 2'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:52:46', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8fb43577-23be-40d6-b7e5-1304d58c76f3'	System	09 Sep 2020 20:53:10
User entered 'Yes (Y)'	System	09 Sep 2020 20:53:10

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:52:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8fb43577-23be-40d6-b7e5-1304d58c76f3'	System	09 Sep 2020 20:53:10
User entered '98.8'	System	09 Sep 2020 20:53:10

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:53:03', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8fb43577-23be-40d6-b7e5-1304d58c76f3'	System	09 Sep 2020 20:53:10
User entered 'No (N)'	System	09 Sep 2020 20:53:10

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:53:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8fb43577-23be-40d6-b7e5-1304d58c76f3'	System	09 Sep 2020 20:53:10
User entered '09 Sep 2020 16:53'	System	09 Sep 2020 20:53:10

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 3'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:11', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4e29251-e465-4978-8f78-11bbfe341f0b'	System	10 Sep 2020 20:12:28
User entered 'Yes (Y)'	System	10 Sep 2020 20:12:28

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4e29251-e465-4978-8f78-11bbfe341f0b'	System	10 Sep 2020 20:12:28
User entered '97.4'	System	10 Sep 2020 20:12:28

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:20', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4e29251-e465-4978-8f78-11bbfe341f0b'	System	10 Sep 2020 20:12:28
User entered 'No (N)'	System	10 Sep 2020 20:12:28

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a4e29251-e465-4978-8f78-11bbfe341f0b'	System	10 Sep 2020 20:12:28
User entered '10 Sep 2020 16:12'	System	10 Sep 2020 20:12:28

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 4'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:32:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '70cf157e-d11f-4c66-8b27-5a0818041f31'	System	12 Sep 2020 01:34:58
User entered 'Yes (Y)'	System	12 Sep 2020 01:34:58

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:34:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '70cf157e-d11f-4c66-8b27-5a0818041f31'	System	12 Sep 2020 01:34:58
User entered '97.2'	System	12 Sep 2020 01:34:58

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:34:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '70cf157e-d11f-4c66-8b27-5a0818041f31'	System	12 Sep 2020 01:34:58
User entered 'No (N)'	System	12 Sep 2020 01:34:58

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:34:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '70cf157e-d11f-4c66-8b27-5a0818041f31'	System	12 Sep 2020 01:34:58
User entered '11 Sep 2020 21:34'	System	12 Sep 2020 01:34:58

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 5'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '10ed855d-3aad-49ec-9fcb-b332b7999dce'	System	12 Sep 2020 20:56:23
User entered 'Yes (Y)'	System	12 Sep 2020 20:56:23

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '10ed855d-3aad-49ec-9fcb-b332b7999dce'	System	12 Sep 2020 20:56:23
User entered '97.9'	System	12 Sep 2020 20:56:23

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '10ed855d-3aad-49ec-9fcb-b332b7999dce'	System	12 Sep 2020 20:56:23
User entered 'No (N)'	System	12 Sep 2020 20:56:23

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '10ed855d-3aad-49ec-9fcb-b332b7999dce'	System	12 Sep 2020 20:56:23
User entered '12 Sep 2020 16:56'	System	12 Sep 2020 20:56:23

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 6'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:55:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'da791032-a389-499e-a200-9bc8644c7a08'	System	13 Sep 2020 22:56:29
User entered 'Yes (Y)'	System	13 Sep 2020 22:56:29

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'da791032-a389-499e-a200-9bc8644c7a08'	System	13 Sep 2020 22:56:29
User entered '97.9'	System	13 Sep 2020 22:56:29

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'da791032-a389-499e-a200-9bc8644c7a08'	System	13 Sep 2020 22:56:29
User entered 'No (N)'	System	13 Sep 2020 22:56:29

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'da791032-a389-499e-a200-9bc8644c7a08'	System	13 Sep 2020 22:56:29
User entered '13 Sep 2020 18:56'	System	13 Sep 2020 22:56:29

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 7'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:06:08', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de2eabb9-2119-408f-b7e9-e363d3878fb7'	System	14 Sep 2020 22:07:15
User entered 'Yes (Y)'	System	14 Sep 2020 22:07:15

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de2eabb9-2119-408f-b7e9-e363d3878fb7'	System	14 Sep 2020 22:07:15
User entered '98.0'	System	14 Sep 2020 22:07:15

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de2eabb9-2119-408f-b7e9-e363d3878fb7'	System	14 Sep 2020 22:07:15
User entered 'No (N)'	System	14 Sep 2020 22:07:15

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de2eabb9-2119-408f-b7e9-e363d3878fb7'	System	14 Sep 2020 22:07:15
User entered '14 Sep 2020 18:07'	System	14 Sep 2020 22:07:15

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572'	System	08 Sep 2020 13:16:51
User entered 'None (1)'	System	08 Sep 2020 13:16:51

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:27', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572'	System	08 Sep 2020 13:16:51
User entered 'No (N)'	System	08 Sep 2020 13:16:51

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572'	System	08 Sep 2020 13:16:51
User entered 'No (N)'	System	08 Sep 2020 13:16:51

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572'	System	08 Sep 2020 13:16:51
User entered 'None (1)'	System	08 Sep 2020 13:16:51

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'b1ef32bf-1857-4ad8-a477-438a21b66572'	System	08 Sep 2020 13:16:51
User entered '08 Sep 2020 09:16'	System	08 Sep 2020 13:16:51

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 09:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 11:30'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:11:18', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195'	System	08 Sep 2020 23:12:48
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 23:12:48

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:11:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195'	System	08 Sep 2020 23:12:48
User entered 'No (N)'	System	08 Sep 2020 23:12:48

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:11:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195'	System	08 Sep 2020 23:12:48
User entered 'Yes (Y)'	System	08 Sep 2020 23:12:48

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:11:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195'	System	08 Sep 2020 23:12:48
User entered '4'	System	08 Sep 2020 23:12:48

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:12:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195'	System	08 Sep 2020 23:12:48
User entered 'None (1)'	System	08 Sep 2020 23:12:48

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:12:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1e4bde11-3a1a-4e36-9d77-8c30476c2195'	System	08 Sep 2020 23:12:48
User entered '08 Sep 2020 19:12'	System	08 Sep 2020 23:12:48

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 12:25'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 2'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:53:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2'	System	09 Sep 2020 20:56:07
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 20:56:07

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:53:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2'	System	09 Sep 2020 20:56:07
User entered 'No (N)'	System	09 Sep 2020 20:56:07

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:55:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2'	System	09 Sep 2020 20:56:07
User entered 'Yes (Y)'	System	09 Sep 2020 20:56:07

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:55:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2'	System	09 Sep 2020 20:56:07
User entered '5'	System	09 Sep 2020 20:56:07

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:55:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2'	System	09 Sep 2020 20:56:07
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 20:56:07

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '23f70677-7580-4c2d-a2ce-81d395a241d2'	System	09 Sep 2020 20:56:07
User entered '09 Sep 2020 16:56'	System	09 Sep 2020 20:56:07

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 3'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec'	System	10 Sep 2020 20:13:47
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 20:13:47

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:38', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec'	System	10 Sep 2020 20:13:47
User entered 'No (N)'	System	10 Sep 2020 20:13:47

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:12:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec'	System	10 Sep 2020 20:13:47
User entered 'Yes (Y)'	System	10 Sep 2020 20:13:47

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:13:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec'	System	10 Sep 2020 20:13:47
User entered '5'	System	10 Sep 2020 20:13:47

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:13:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec'	System	10 Sep 2020 20:13:47
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 20:13:47

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:13:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b65c745-24ac-4c89-b2d9-b6415d3eb1ec'	System	10 Sep 2020 20:13:47
User entered '10 Sep 2020 16:13'	System	10 Sep 2020 20:13:47

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 4'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:35:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f'	System	12 Sep 2020 01:36:05
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 01:36:05

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:35:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f'	System	12 Sep 2020 01:36:05
User entered 'No (N)'	System	12 Sep 2020 01:36:05

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:35:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f'	System	12 Sep 2020 01:36:05
User entered 'Yes (Y)'	System	12 Sep 2020 01:36:05

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:35:46', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f' User entered '30'	System	12 Sep 2020 01:36:05

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:35:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f'	System	12 Sep 2020 01:36:05
User entered 'None (1)'	System	12 Sep 2020 01:36:05

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61135e64-40e7-469b-afdf-0ff953ff5c3f'	System	12 Sep 2020 01:36:05
User entered '11 Sep 2020 21:36'	System	12 Sep 2020 01:36:05

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 5'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715'	System	12 Sep 2020 20:56:46
User entered 'None (1)'	System	12 Sep 2020 20:56:46

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715'	System	12 Sep 2020 20:56:46
User entered 'No (N)'	System	12 Sep 2020 20:56:46

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715'	System	12 Sep 2020 20:56:46
User entered 'No (N)'	System	12 Sep 2020 20:56:46

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715'	System	12 Sep 2020 20:56:46
User entered 'None (1)'	System	12 Sep 2020 20:56:46

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1ae92e04-cb71-4c9a-963e-7a6a389cd715'	System	12 Sep 2020 20:56:46
User entered '12 Sep 2020 16:56'	System	12 Sep 2020 20:56:46

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 6'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:32', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0'	System	13 Sep 2020 22:56:50
User entered 'None (1)'	System	13 Sep 2020 22:56:50

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0'	System	13 Sep 2020 22:56:50
User entered 'No (N)'	System	13 Sep 2020 22:56:50

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0'	System	13 Sep 2020 22:56:50
User entered 'No (N)'	System	13 Sep 2020 22:56:50

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0'	System	13 Sep 2020 22:56:50
User entered 'None (1)'	System	13 Sep 2020 22:56:50

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'd8df50ed-a5f0-4ee8-9ef7-9265904b71a0'	System	13 Sep 2020 22:56:50
User entered '13 Sep 2020 18:56'	System	13 Sep 2020 22:56:50

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 7'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e'	System	14 Sep 2020 22:07:52
User entered 'None (1)'	System	14 Sep 2020 22:07:52

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e'	System	14 Sep 2020 22:07:52
User entered 'No (N)'	System	14 Sep 2020 22:07:52

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:33', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e'	System	14 Sep 2020 22:07:52
User entered 'No (N)'	System	14 Sep 2020 22:07:52

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:42', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e'	System	14 Sep 2020 22:07:52
User entered 'None (1)'	System	14 Sep 2020 22:07:52

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:47', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '5665902c-be2b-45c5-8591-ecf1b8a57b4e'	System	14 Sep 2020 22:07:52
User entered '14 Sep 2020 18:07'	System	14 Sep 2020 22:07:52

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:16:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907'	System	08 Sep 2020 13:17:57
User entered 'None (0)'	System	08 Sep 2020 13:17:57

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907'	System	08 Sep 2020 13:17:57
User entered 'None (0)'	System	08 Sep 2020 13:17:57

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:24', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907'	System	08 Sep 2020 13:17:57
User entered 'None (0)'	System	08 Sep 2020 13:17:57

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:38', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907'	System	08 Sep 2020 13:17:57
User entered 'None (0)'	System	08 Sep 2020 13:17:57

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:41', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907'	System	08 Sep 2020 13:17:57
User entered 'None (0)'	System	08 Sep 2020 13:17:57

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907'	System	08 Sep 2020 13:17:57
User entered 'None (0)'	System	08 Sep 2020 13:17:57

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907'	System	08 Sep 2020 13:17:57
User entered 'No (N)'	System	08 Sep 2020 13:17:57

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T09:17:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '937ed021-75ec-4d98-8031-3b0ea56b8907'	System	08 Sep 2020 13:17:57
User entered '08 Sep 2020 09:17'	System	08 Sep 2020 13:17:57

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 09:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 11:30'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:12:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289'	System	08 Sep 2020 23:13:27
User entered 'No interference with activity (1)'	System	08 Sep 2020 23:13:27

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:12:59', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289'	System	08 Sep 2020 23:13:27
User entered 'None (0)'	System	08 Sep 2020 23:13:27

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289'	System	08 Sep 2020 23:13:27
User entered 'None (0)'	System	08 Sep 2020 23:13:27

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289'	System	08 Sep 2020 23:13:27
User entered 'None (0)'	System	08 Sep 2020 23:13:27

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289'	System	08 Sep 2020 23:13:27
User entered 'None (0)'	System	08 Sep 2020 23:13:27

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289'	System	08 Sep 2020 23:13:27
User entered 'None (0)'	System	08 Sep 2020 23:13:27

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289'	System	08 Sep 2020 23:13:27
User entered 'No (N)'	System	08 Sep 2020 23:13:27

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-08T19:13:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'fe6677a9-2f5b-412b-be58-37872b19f289'	System	08 Sep 2020 23:13:27
User entered '08 Sep 2020 19:13'	System	08 Sep 2020 23:13:27

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '08 Sep 2020 12:25'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 2'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117'	System	09 Sep 2020 20:57:05
User entered 'No interference with activity (1)'	System	09 Sep 2020 20:57:05

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117'	System	09 Sep 2020 20:57:05
User entered 'Some interference with activity (2)'	System	09 Sep 2020 20:57:05

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117'	System	09 Sep 2020 20:57:05
User entered 'No interference with activity (1)'	System	09 Sep 2020 20:57:05

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117'	System	09 Sep 2020 20:57:05
User entered 'None (0)'	System	09 Sep 2020 20:57:05

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117'	System	09 Sep 2020 20:57:05
User entered 'None (0)'	System	09 Sep 2020 20:57:05

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117'	System	09 Sep 2020 20:57:05
User entered 'No interference with activity (1)'	System	09 Sep 2020 20:57:05

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:56:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117'	System	09 Sep 2020 20:57:05
User entered 'No (N)'	System	09 Sep 2020 20:57:05

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-09T16:57:03', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ce763bd8-fc7c-4f2c-9c20-742d68aac117'	System	09 Sep 2020 20:57:05
User entered '09 Sep 2020 16:57'	System	09 Sep 2020 20:57:05

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 3'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:13:50', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30'	System	10 Sep 2020 20:14:38
User entered 'No interference with activity (1)'	System	10 Sep 2020 20:14:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:08', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30'	System	10 Sep 2020 20:14:38
User entered 'None (0)'	System	10 Sep 2020 20:14:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:13', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30'	System	10 Sep 2020 20:14:38
User entered 'None (0)'	System	10 Sep 2020 20:14:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30'	System	10 Sep 2020 20:14:38
User entered 'None (0)'	System	10 Sep 2020 20:14:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30'	System	10 Sep 2020 20:14:38
User entered 'None (0)'	System	10 Sep 2020 20:14:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30'	System	10 Sep 2020 20:14:38
User entered 'None (0)'	System	10 Sep 2020 20:14:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30'	System	10 Sep 2020 20:14:38
User entered 'No (N)'	System	10 Sep 2020 20:14:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-10T16:14:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '43bff529-0175-4872-9619-651e1f57be30'	System	10 Sep 2020 20:14:38
User entered '10 Sep 2020 16:14'	System	10 Sep 2020 20:14:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 4'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:15', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058'	System	12 Sep 2020 01:36:41
User entered 'None (0)'	System	12 Sep 2020 01:36:41

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058'	System	12 Sep 2020 01:36:41
User entered 'None (0)'	System	12 Sep 2020 01:36:41

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:22', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058'	System	12 Sep 2020 01:36:41
User entered 'None (0)'	System	12 Sep 2020 01:36:41

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058'	System	12 Sep 2020 01:36:41
User entered 'None (0)'	System	12 Sep 2020 01:36:41

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058'	System	12 Sep 2020 01:36:41
User entered 'None (0)'	System	12 Sep 2020 01:36:41

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058'	System	12 Sep 2020 01:36:41
User entered 'None (0)'	System	12 Sep 2020 01:36:41

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:34', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058'	System	12 Sep 2020 01:36:41
User entered 'No (N)'	System	12 Sep 2020 01:36:41

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-11T21:36:39', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ff130702-1a72-4d00-b778-33e63631c058'	System	12 Sep 2020 01:36:41
User entered '11 Sep 2020 21:36'	System	12 Sep 2020 01:36:41

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 5'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:49', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d'	System	12 Sep 2020 20:57:38
User entered 'None (0)'	System	12 Sep 2020 20:57:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d'	System	12 Sep 2020 20:57:38
User entered 'None (0)'	System	12 Sep 2020 20:57:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d'	System	12 Sep 2020 20:57:38
User entered 'None (0)'	System	12 Sep 2020 20:57:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:56:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d'	System	12 Sep 2020 20:57:38
User entered 'None (0)'	System	12 Sep 2020 20:57:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:57:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d'	System	12 Sep 2020 20:57:38
User entered 'None (0)'	System	12 Sep 2020 20:57:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:57:03', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d'	System	12 Sep 2020 20:57:38
User entered 'None (0)'	System	12 Sep 2020 20:57:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:57:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d'	System	12 Sep 2020 20:57:38
User entered 'Yes (Y)'	System	12 Sep 2020 20:57:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-12T16:57:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '90672760-5ddb-4e83-bf34-8f094af4d94d'	System	12 Sep 2020 20:57:38
User entered '12 Sep 2020 16:57'	System	12 Sep 2020 20:57:38

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 6'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:52', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359'	System	13 Sep 2020 22:57:19
User entered 'None (0)'	System	13 Sep 2020 22:57:19

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359'	System	13 Sep 2020 22:57:19
User entered 'None (0)'	System	13 Sep 2020 22:57:19

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:56:59', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359'	System	13 Sep 2020 22:57:19
User entered 'None (0)'	System	13 Sep 2020 22:57:19

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359'	System	13 Sep 2020 22:57:19
User entered 'None (0)'	System	13 Sep 2020 22:57:19

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359'	System	13 Sep 2020 22:57:19
User entered 'None (0)'	System	13 Sep 2020 22:57:19

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:07', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359'	System	13 Sep 2020 22:57:19
User entered 'None (0)'	System	13 Sep 2020 22:57:19

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359'	System	13 Sep 2020 22:57:19
User entered 'No (N)'	System	13 Sep 2020 22:57:19

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-13T18:57:17', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'de39f6ee-6f44-42de-ba2e-c0c525fe4359'	System	13 Sep 2020 22:57:19
User entered '13 Sep 2020 18:57'	System	13 Sep 2020 22:57:19

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	08 Sep 2020 12:52:12
User entered 'Day 7'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:52', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26'	System	14 Sep 2020 22:08:22
User entered 'None (0)'	System	14 Sep 2020 22:08:22

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26'	System	14 Sep 2020 22:08:22
User entered 'None (0)'	System	14 Sep 2020 22:08:22

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:07:58', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26'	System	14 Sep 2020 22:08:22
User entered 'None (0)'	System	14 Sep 2020 22:08:22

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26'	System	14 Sep 2020 22:08:22
User entered 'None (0)'	System	14 Sep 2020 22:08:22

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26'	System	14 Sep 2020 22:08:22
User entered 'None (0)'	System	14 Sep 2020 22:08:22

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26'	System	14 Sep 2020 22:08:22
User entered 'None (0)'	System	14 Sep 2020 22:08:22

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:15', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26'	System	14 Sep 2020 22:08:22
User entered 'No (N)'	System	14 Sep 2020 22:08:22

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-09-14T18:08:19', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1b22e2e2-9e12-41ee-b05e-6eb0f3344f26'	System	14 Sep 2020 22:08:22
User entered '14 Sep 2020 18:08'	System	14 Sep 2020 22:08:22

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 12:52:12

US3532002

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:06:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 12:52:12

US3532002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:40:31

US3532002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '15 Sep 2020'	Lisa Macoy (b) (4)	12 Oct 2020 17:40:31

US3532002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	12 Oct 2020 17:40:31

US3532002

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	12 Oct 2020 17:40:31

US3532002

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:40:40

US3532002

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	12 Oct 2020 17:40:40

US3532002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:41:04

US3532002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '22 Sep 2020'	Lisa Macoy (b) (4)	12 Oct 2020 17:41:04

US3532002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	12 Oct 2020 17:41:04

US3532002

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	12 Oct 2020 17:41:04
	(b) (4)	

US3532002

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:41:13

US3532002

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	12 Oct 2020 17:41:13

US3532002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:41:43

US3532002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '29 Sep 2020'	Lisa Macoy (b) (4)	12 Oct 2020 17:41:43

US3532002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	12 Oct 2020 17:41:43

US3532002

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	12 Oct 2020 17:41:43

US3532002

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:41:49

US3532002

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	12 Oct 2020 17:41:49

US3532002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:42:04

US3532002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '12 Oct 2020'	Lisa Macoy (b) (4)	12 Oct 2020 17:42:04

US3532002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	12 Oct 2020 17:42:04

US3532002

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'VISIT3'	System	12 Oct 2020 17:42:04

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '12 Oct 2020'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '12:33'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '12 Oct 2020 12:33'	System	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '97.6' F	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '72'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'bpm'	System	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '20'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'breaths/min'	System	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '146'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '86'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'mmHg'	System	12 Oct 2020 17:43:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04

US3532002

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04

US3532002

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'No (N)'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:27

US3532002

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered empty.	Lisa Macoy (b) (4)	12 Oct 2020 17:43:27

US3532002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:59

US3532002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '12 Oct 2020'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:59

US3532002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered '12:47'	Lisa Macoy (b) (4)	12 Oct 2020 17:43:59

US3532002

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered '12 Oct 2020 12:47'	System	12 Oct 2020 17:43:59

US3532002

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:59:03
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 17:44:12

US3532002

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	12 Oct 2020 17:44:12

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 64'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-10-13T20:27:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '0e6c64bd-cd87-40f6-b82b-220d41e1230c'	System	14 Oct 2020 00:27:58
User entered 'No (N)'	System	14 Oct 2020 00:27:58

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-10-13T20:27:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '0e6c64bd-cd87-40f6-b82b-220d41e1230c'	System	14 Oct 2020 00:27:58
User entered 'No (N)'	System	14 Oct 2020 00:27:58

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-10-13T20:27:53', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '0e6c64bd-cd87-40f6-b82b-220d41e1230c' User entered '13 Oct 2020 20:27:53'	System	14 Oct 2020 00:27:58
	System	14 Oct 2020 00:27:58

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 71'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-10-18T00:02:08', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '49c44d92-382c-4216-a248-e3a3569473f3'	System	18 Oct 2020 04:02:24
User entered 'No (N)'	System	18 Oct 2020 04:02:24

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-10-18T00:02:14', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '49c44d92-382c-4216-a248-e3a3569473f3'	System	18 Oct 2020 04:02:24
User entered 'No (N)'	System	18 Oct 2020 04:02:24

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5546d99a3480aa1e)', Time: '2020-10-18T00:02:18', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '49c44d92-382c-4216-a248-e3a3569473f3'	System	18 Oct 2020 04:02:24
User entered '18 Oct 2020 00:02:18'	System	18 Oct 2020 04:02:24

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 78'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-10-26T14:15:40', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0bfe567-f6e3-42d9-9622-1a51262600e7'	System	26 Oct 2020 18:15:51
User entered 'No (N)'	System	26 Oct 2020 18:15:51

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-10-26T14:15:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0bfe567-f6e3-42d9-9622-1a51262600e7'	System	26 Oct 2020 18:15:51
User entered 'No (N)'	System	26 Oct 2020 18:15:51

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-10-26T14:15:48', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a0bfe567-f6e3-42d9-9622-1a51262600e7' User entered '26 Oct 2020 14:15:48'	System	26 Oct 2020 18:15:51
	System	26 Oct 2020 18:15:51

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 92'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-08T15:16:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1f88b0a6-bb8b-474a-a9b2-9cfdefae4b6b'	System	08 Nov 2020 20:16:38
User entered 'No (N)'	System	08 Nov 2020 20:16:38

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-08T15:16:29', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1f88b0a6-bb8b-474a-a9b2-9cfdefae4b6b'	System	08 Nov 2020 20:16:38
User entered 'No (N)'	System	08 Nov 2020 20:16:38

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-08T15:16:35', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1f88b0a6-bb8b-474a-a9b2-9cfdefae4b6b'	System	08 Nov 2020 20:16:38
User entered '08 Nov 2020 15:16:35'	System	08 Nov 2020 20:16:38

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered 'Day 99'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-15T18:52:54', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a2c71669-632f-424c-9449-d74d26e98160'	System	15 Nov 2020 23:53:09
User entered 'No (N)'	System	15 Nov 2020 23:53:09

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-15T18:52:58', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a2c71669-632f-424c-9449-d74d26e98160'	System	15 Nov 2020 23:53:09
User entered 'No (N)'	System	15 Nov 2020 23:53:09

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-15T18:53:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a2c71669-632f-424c-9449-d74d26e98160'	System	15 Nov 2020 23:53:09
User entered '15 Nov 2020 18:53:04'	System	15 Nov 2020 23:53:09

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 22:10:10

US3532002

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:19:48
Data entry locked.	System	11 Aug 2020 22:10:10
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 22:10:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2020-11-19T18:58:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '275bd0af-68e8-4293-b1bb-03dba9dcdf98'	System	20 Nov 2020 00:59:09
User entered 'No (N)'	System	20 Nov 2020 00:59:09

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-11-19T18:59:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '275bd0af-68e8-4293-b1bb-03dba9dcdf98'	System	20 Nov 2020 00:59:09
User entered 'No (N)'	System	20 Nov 2020 00:59:09

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-19T18:59:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '275bd0af-68e8-4293-b1bb-03dba9dcd98'	System	20 Nov 2020 00:59:09
User entered '19 Nov 2020 18:59:04'	System	20 Nov 2020 00:59:09

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2020-11-26T18:36:28', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f7434914-bbb4-4ed6-a659-81727b97327b'	System	26 Nov 2020 23:36:46
User entered 'No (N)'	System	26 Nov 2020 23:36:46

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-11-26T18:36:37', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f7434914-bbb4-4ed6-a659-81727b97327b'	System	26 Nov 2020 23:36:46
User entered 'No (N)'	System	26 Nov 2020 23:36:46

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-11-26T18:36:41', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f7434914-bbb4-4ed6-a659-81727b97327b'	System	26 Nov 2020 23:36:46
User entered '26 Nov 2020 18:36:41'	System	26 Nov 2020 23:36:46

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2020-12-03T06:15:12', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cfe8fc23-513b-44bc-adfe-ea602de27825'	System	03 Dec 2020 11:15:31
User entered 'No (N)'	System	03 Dec 2020 11:15:31

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-12-03T06:15:23', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cfe8fc23-513b-44bc-adfe-ea602de27825'	System	03 Dec 2020 11:15:31
User entered 'No (N)'	System	03 Dec 2020 11:15:31

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-12-03T06:15:27', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'cfe8fc23-513b-44bc-adfe-ea602de27825'	System	03 Dec 2020 11:15:31
User entered '03 Dec 2020 06:15:27'	System	03 Dec 2020 11:15:31

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2020-12-10T10:25:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e248b4bd-5af0-446d-892b-3fab8c3fa726'	System	10 Dec 2020 15:25:41
User entered 'No (N)'	System	10 Dec 2020 15:25:41

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-12-10T10:25:30', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e248b4bd-5af0-446d-892b-3fab8c3fa726'	System	10 Dec 2020 15:25:41
User entered 'No (N)'	System	10 Dec 2020 15:25:41

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-12-10T10:25:36', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e248b4bd-5af0-446d-892b-3fab8c3fa726'	System	10 Dec 2020 15:25:41
User entered '10 Dec 2020 10:25:36'	System	10 Dec 2020 15:25:41

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2020-12-17T06:03:57', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e4fb34af-3b4f-49a6-8ecc-43c4b131e65a'	System	17 Dec 2020 11:04:10
User entered 'No (N)'	System	17 Dec 2020 11:04:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-12-17T06:04:04', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e4fb34af-3b4f-49a6-8ecc-43c4b131e65a'	System	17 Dec 2020 11:04:10
User entered 'No (N)'	System	17 Dec 2020 11:04:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-12-17T06:04:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e4fb34af-3b4f-49a6-8ecc-43c4b131e65a'	System	17 Dec 2020 11:04:10
User entered '17 Dec 2020 06:04:09'	System	17 Dec 2020 11:04:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2020-12-24T03:58:06', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e2783b61-d445-4f2b-81a0-3863c116352e'	System	24 Dec 2020 08:58:29
User entered 'No (N)'	System	24 Dec 2020 08:58:29

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2020-12-24T03:58:20', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e2783b61-d445-4f2b-81a0-3863c116352e'	System	24 Dec 2020 08:58:29
User entered 'No (N)'	System	24 Dec 2020 08:58:29

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2020-12-24T03:58:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e2783b61-d445-4f2b-81a0-3863c116352e'	System	24 Dec 2020 08:58:29
User entered '24 Dec 2020 03:58:26'	System	24 Dec 2020 08:58:29

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-01-04T18:54:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ba155ab2-3da9-4971-afa8-536d3e1c62e8'	System	04 Jan 2021 23:55:25
User entered 'No (N)'	System	04 Jan 2021 23:55:25

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-01-04T18:55:21', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ba155ab2-3da9-4971-afa8-536d3e1c62e8'	System	04 Jan 2021 23:55:25
User entered 'No (N)'	System	04 Jan 2021 23:55:25

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-01-04T18:55:25', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'ba155ab2-3da9-4971-afa8-536d3e1c62e8'	System	04 Jan 2021 23:55:25
User entered '04 Jan 2021 18:55:25'	System	04 Jan 2021 23:55:25

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-01-07T08:00:45', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c550a5f-023d-4a99-8860-1246a958c9be'	System	07 Jan 2021 13:00:56
User entered 'No (N)'	System	07 Jan 2021 13:00:56

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-01-07T08:00:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c550a5f-023d-4a99-8860-1246a958c9be'	System	07 Jan 2021 13:00:56
User entered 'No (N)'	System	07 Jan 2021 13:00:56

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-01-07T08:00:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6c550a5f-023d-4a99-8860-1246a958c9be'	System	07 Jan 2021 13:00:56
User entered '07 Jan 2021 08:00:56'	System	07 Jan 2021 13:00:56

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-01-14T16:28:31', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6715752f-51a5-4a10-80b4-881f8618e8db'	System	14 Jan 2021 21:29:18
User entered 'No (N)'	System	14 Jan 2021 21:29:18

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-01-14T16:28:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6715752f-51a5-4a10-80b4-881f8618e8db'	System	14 Jan 2021 21:29:18
User entered 'No (N)'	System	14 Jan 2021 21:29:18

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-01-14T16:29:15', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6715752f-51a5-4a10-80b4-881f8618e8db'	System	14 Jan 2021 21:29:18
User entered '14 Jan 2021 16:29:15'	System	14 Jan 2021 21:29:18

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-01-21T07:18:51', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '85b784b4-8fea-4e2b-b385-32619839a678'	System	21 Jan 2021 12:19:10
User entered 'No (N)'	System	21 Jan 2021 12:19:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-01-21T07:19:02', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '85b784b4-8fea-4e2b-b385-32619839a678'	System	21 Jan 2021 12:19:10
User entered 'No (N)'	System	21 Jan 2021 12:19:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-01-21T07:19:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '85b784b4-8fea-4e2b-b385-32619839a678'	System	21 Jan 2021 12:19:10
User entered '21 Jan 2021 07:19:05'	System	21 Jan 2021 12:19:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-01-29T12:19:44', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61bca218-1bd7-48b1-88f8-1645fc78b89b'	System	29 Jan 2021 17:20:07
User entered 'No (N)'	System	29 Jan 2021 17:20:07

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-01-29T12:19:55', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61bca218-1bd7-48b1-88f8-1645fc78b89b'	System	29 Jan 2021 17:20:07
User entered 'No (N)'	System	29 Jan 2021 17:20:07

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-01-29T12:20:01', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '61bca218-1bd7-48b1-88f8-1645fc78b89b'	System	29 Jan 2021 17:20:07
User entered '29 Jan 2021 12:20:01'	System	29 Jan 2021 17:20:07

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-02-11T22:47:56', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'c4e82199-79dc-490c-bbd6-8f1802c2eb66'	System	12 Feb 2021 03:48:14
User entered 'No (N)'	System	12 Feb 2021 03:48:14

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-02-11T22:48:05', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'c4e82199-79dc-490c-bbd6-8f1802c2eb66'	System	12 Feb 2021 03:48:14
User entered 'No (N)'	System	12 Feb 2021 03:48:14

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-02-11T22:48:09', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'c4e82199-79dc-490c-bbd6-8f1802c2eb66'	System	12 Feb 2021 03:48:14
User entered '11 Feb 2021 22:48:09'	System	12 Feb 2021 03:48:14

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-02-18T10:16:16', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b3a5a06-4f4d-44f1-af9c-26e811a1d713'	System	18 Feb 2021 15:16:29
User entered 'No (N)'	System	18 Feb 2021 15:16:29

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-02-18T10:16:20', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b3a5a06-4f4d-44f1-af9c-26e811a1d713'	System	18 Feb 2021 15:16:29
User entered 'No (N)'	System	18 Feb 2021 15:16:29

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-02-18T10:16:26', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '6b3a5a06-4f4d-44f1-af9c-26e811a1d713'	System	18 Feb 2021 15:16:29
User entered '18 Feb 2021 10:16:26'	System	18 Feb 2021 15:16:29

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-02-25T09:11:33-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'dc8129c4-ef91-4d4a-bee8-b346ae661f01'	System	25 Feb 2021 14:11:48
User entered 'No (N)'	System	25 Feb 2021 14:11:48

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-02-25T09:11:36-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'dc8129c4-ef91-4d4a-bee8-b346ae661f01'	System	25 Feb 2021 14:11:48
User entered 'No (N)'	System	25 Feb 2021 14:11:48

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-02-25T09:11:41-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'dc8129c4-ef91-4d4a-bee8-b346ae661f01'	System	25 Feb 2021 14:11:48
User entered '25 Feb 2021 09:11:41'	System	25 Feb 2021 14:11:48

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-03-04T07:00:30-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c7f273e-6325-4f27-9cd6-14f876065d2b'	System	04 Mar 2021 12:01:09
User entered 'No (N)'	System	04 Mar 2021 12:01:09

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-03-04T07:00:35-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c7f273e-6325-4f27-9cd6-14f876065d2b'	System	04 Mar 2021 12:01:09
User entered 'No (N)'	System	04 Mar 2021 12:01:09

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-03-04T07:00:39-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '8c7f273e-6325-4f27-9cd6-14f876065d2b' User entered '04 Mar 2021 07:00:39'	System	04 Mar 2021 12:01:09
	System	04 Mar 2021 12:01:09

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-03-12T13:36:18-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a5f73d60-a1ee-4488-b3c4-5c99da230d12'	System	12 Mar 2021 18:36:54
User entered 'No (N)'	System	12 Mar 2021 18:36:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-03-12T13:36:23-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a5f73d60-a1ee-4488-b3c4-5c99da230d12'	System	12 Mar 2021 18:36:54
User entered 'No (N)'	System	12 Mar 2021 18:36:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-03-12T13:36:28-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'a5f73d60-a1ee-4488-b3c4-5c99da230d12'	System	12 Mar 2021 18:36:54
User entered '12 Mar 2021 13:36:28'	System	12 Mar 2021 18:36:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-03-18T07:55:43-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '27d3f3cd-94e0-44a9-bb83-c260f959b018'	System	18 Mar 2021 11:55:59
User entered 'No (N)'	System	18 Mar 2021 11:55:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-03-18T07:55:53-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '27d3f3cd-94e0-44a9-bb83-c260f959b018'	System	18 Mar 2021 11:55:59
User entered 'No (N)'	System	18 Mar 2021 11:55:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-03-18T07:55:56-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '27d3f3cd-94e0-44a9-bb83-c260f959b018'	System	18 Mar 2021 11:55:59
User entered '18 Mar 2021 07:55:56'	System	18 Mar 2021 11:55:59

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-03-29T11:36:40-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1c3c8f80-c07c-4ef3-b0da-b90e27c16be8'	System	29 Mar 2021 15:36:57
User entered 'No (N)'	System	29 Mar 2021 15:36:57

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-03-29T11:36:48-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1c3c8f80-c07c-4ef3-b0da-b90e27c16be8'	System	29 Mar 2021 15:36:57
User entered 'No (N)'	System	29 Mar 2021 15:36:57

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-03-29T11:36:53-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '1c3c8f80-c07c-4ef3-b0da-b90e27c16be8' User entered '29 Mar 2021 11:36:53'	System	29 Mar 2021 15:36:57
	System	29 Mar 2021 15:36:57

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-04-01T09:23:25-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '02ae6660-186b-4e3e-be92-5bb9fd08eda8'	System	01 Apr 2021 13:23:37
User entered 'No (N)'	System	01 Apr 2021 13:23:37

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-04-01T09:23:33-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '02ae6660-186b-4e3e-be92-5bb9fd08eda8'	System	01 Apr 2021 13:23:37
User entered 'No (N)'	System	01 Apr 2021 13:23:37

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-04-01T09:23:35-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '02ae6660-186b-4e3e-be92-5bb9fd08eda8'	System	01 Apr 2021 13:23:37
User entered '01 Apr 2021 09:23:35'	System	01 Apr 2021 13:23:37

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-04-17T12:42:40-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '3433bbd9-4163-448c-adb2-1b45a346c5cf' User entered 'No (N)'	System	17 Apr 2021 16:42:54
	System	17 Apr 2021 16:42:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-04-17T12:42:48-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '3433bbd9-4163-448c-adb2-1b45a346c5cf'	System	17 Apr 2021 16:42:54
User entered 'No (N)'	System	17 Apr 2021 16:42:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-04-17T12:42:52-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: '3433bbd9-4163-448c-adb2-1b45a346c5cf' User entered '17 Apr 2021 12:42:52'	System	17 Apr 2021 16:42:54
	System	17 Apr 2021 16:42:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-04-22T13:32:32-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f3ab5e9a-322e-4d68-a24a-f88349f2d123'	System	22 Apr 2021 17:32:54
User entered 'No (N)'	System	22 Apr 2021 17:32:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-04-22T13:32:44-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f3ab5e9a-322e-4d68-a24a-f88349f2d123'	System	22 Apr 2021 17:32:54
User entered 'No (N)'	System	22 Apr 2021 17:32:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-04-22T13:32:49-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'f3ab5e9a-322e-4d68-a24a-f88349f2d123'	System	22 Apr 2021 17:32:54
User entered '22 Apr 2021 13:32:49'	System	22 Apr 2021 17:32:54

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[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 (e4a121161252b7b0)', Time: '2021-04-30T18:31:10-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'aa8c7ebd-cf07-44be-897c-423c9ebbb1e9'	System	30 Apr 2021 22:31:19
User entered 'No (N)'	System	30 Apr 2021 22:31:19

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

Have you been exposed to someone with 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 (e4a121161252b7b0)', Time: '2021-04-30T18:31:12-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'aa8c7ebd-cf07-44be-897c-423c9ebbb1e9'	System	30 Apr 2021 22:31:19
User entered 'No (N)'	System	30 Apr 2021 22:31:19

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-04-30T18:31:15-04:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'aa8c7ebd-cf07-44be-897c-423c9ebbb1e9'	System	30 Apr 2021 22:31:19
User entered '30 Apr 2021 18:31:15'	System	30 Apr 2021 22:31:19

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:09:10

US3532002

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:06:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:09:10
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:09:10

US3532002

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:06:59

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 10:03:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-03-01T20:10:03-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e0df2a9b-3e18-47af-a194-e7433be80786'	System	02 Mar 2021 01:10:13
User entered 'No (N)'	System	02 Mar 2021 01:10:13

US3532002

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:06:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:03:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4a121161252b7b0)', Time: '2021-03-01T20:10:10-05:00', User OID: 'PatientReportedOutcome (US3532002)', ODM File OID: 'e0df2a9b-3e18-47af-a194-e7433be80786'	System	02 Mar 2021 01:10:13
User entered '01 Mar 2021 20:10:10'	System	02 Mar 2021 01:10:13

US3532002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 06:47:01
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	02 Nov 2020 21:11:54
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	02 Nov 2020 21:11:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	02 Nov 2020 21:11:45
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	Etza Peters (b) (4) (b) (4)	30 Oct 2020 16:35:34
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 16:35:25
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	30 Oct 2020 16:35:25
User entered empty; reason for change Data Entry Error	Etza Peters (b) (4) (b) (4)	30 Oct 2020 16:35:25
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	30 Oct 2020 16:28:59
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	30 Oct 2020 16:28:59

US3532002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '2 Nov 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	02 Nov 2020 21:11:45
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Oct 2020 16:35:25
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	30 Oct 2020 16:35:25
User entered empty; reason for change Data Entry Error	Etza Peters (b) (4)	30 Oct 2020 16:35:25
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Oct 2020 16:28:59
User entered '30 Oct 2020'	Etza Peters (b) (4)	30 Oct 2020 16:28:59

US3532002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Etza Peters (b) (4)	02 Nov 2020 21:11:54
User entered empty.	(b) (4)	
	Etza Peters (b) (4)	30 Oct 2020 16:28:59
	(b) (4)	

US3532002

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	30 Oct 2020 16:28:59

US3532002

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4) (b) (4)	02 Nov 2020 21:11:59

US3532002

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 05:06:04
User entered 'I'	System	02 Nov 2020 21:11:59

US3532002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	10 Dec 2020 16:35:05

US3532002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '10 Dec 2020'	Etza Peters (b) (4)	10 Dec 2020 16:35:05

US3532002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	Etza Peters (b) (4)	10 Dec 2020 16:35:05

US3532002

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 16:35:05

US3532002

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	10 Dec 2020 16:35:11

US3532002

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered 'I'	System	10 Dec 2020 16:35:11

US3532002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	05 Jan 2021 17:52:09

US3532002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '5 Jan 2021'	Etza Peters (b) (4)	05 Jan 2021 17:52:09

US3532002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	Etza Peters (b) (4)	05 Jan 2021 17:52:09

US3532002

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	05 Jan 2021 17:52:09

US3532002

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	05 Jan 2021 17:52:49

US3532002

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered 'I'	System	05 Jan 2021 17:52:49

US3532002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	02 Feb 2021 19:38:19

US3532002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '2 Feb 2021'	Etza Peters (b) (4)	02 Feb 2021 19:38:19

US3532002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Contact Made (CONTACT MADE)'	Etza Peters (b) (4)	02 Feb 2021 19:38:19

US3532002

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	02 Feb 2021 19:38:19

US3532002

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	02 Feb 2021 19:38:25

US3532002

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered 'I'	System	02 Feb 2021 19:38:25

US3532002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered 'Yes (Y)'	Etza Peters (b) (4)	09 Mar 2021 21:03:07

US3532002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered '9 Mar 2021'	Etza Peters (b) (4)	09 Mar 2021 21:03:07

US3532002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered 'Clinic (Clinic)'	Etza Peters (b) (4)	09 Mar 2021 21:03:07

US3532002

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered 'VISIT4'	System	09 Mar 2021 21:03:07

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered 'No (N)'	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered empty.	System	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered empty.	System	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered empty.	System	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered empty.	System	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Laila Hussaini (b) (4)	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered empty.	System	01 Apr 2021 18:10:12

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13

US3532002

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:06:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13

US3532002

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Mar 2021 21:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 21:02:20
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	09 Mar 2021 21:02:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Mar 2021 21:02:17
User entered empty.	System	09 Mar 2021 21:02:17
	Etza Peters (b) (4)	09 Mar 2021 21:02:17
	(b) (4)	

US3532002

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:06:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Etza Peters (b) (4)	09 Mar 2021 21:02:17

US3532002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered 'Yes (Y)'	Etza Peters (b) (4)	09 Mar 2021 21:02:55

US3532002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered '9 Mar 2021'	Etza Peters (b) (4)	09 Mar 2021 21:02:55

US3532002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered '14:58'	Etza Peters (b) (4)	09 Mar 2021 21:02:55

US3532002

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered '9 Mar 2021 14:58'	System	09 Mar 2021 21:02:55

US3532002

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered 'Yes (Y)'	Etza Peters (b) (4)	09 Mar 2021 21:03:01

US3532002

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:13:13
User entered 'I'	System	09 Mar 2021 21:03:01

US3532002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:34:33
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	09 Apr 2021 14:27:45
	(b) (4)	

US3532002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:34:33
	(b) (4)	
User entered '9 Apr 2021'	Kathy Stephens (b) (4)	09 Apr 2021 14:27:45
	(b) (4)	

US3532002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:34:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kathy Stephens (b) (4) (b) (4)	09 Apr 2021 14:27:45

US3532002

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:06:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:34:33
	(b) (4)	
User entered empty.	Kathy Stephens (b) (4)	09 Apr 2021 14:27:45
	(b) (4)	

US3532002

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 08:34:33
	(b) (4)	
User entered 'Yes (Y)'	Kathy Stephens (b) (4)	09 Apr 2021 14:27:55
	(b) (4)	

US3532002

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:06:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:27:55

US3532002

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

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	11 Jan 2021 21:25:23

US3532002

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

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Jan 2021'	Peggy Kettle (b) (4)	11 Jan 2021 21:25:23

US3532002

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

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[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 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Clinic (Clinic)'	Peggy Kettle (b) (4)	11 Jan 2021 21:25:23

US3532002

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

Form: Visit Date

Generated On: 10 Jun 2021 08:06:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 21:25:23

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Jan 2021'	(b) (4) Peggy Kettle (b) (4) (b) (4)	11 Jan 2021 21:25:48

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:49:25

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	11 Jan 2021 21:25:48

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:49:25

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Jan 2021'	(b) (4) Peggy Kettle (b) (4) (b) (4)	11 Jan 2021 21:25:48

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'mRNA-1273 (mRNA-1273)'	Peggy Kettle (b) (4)	11 Jan 2021 21:25:48

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 01:46:55
User entered 'mRNA-1273 (mRNA-1273)'	Peggy Kettle (b) (4)	11 Jan 2021 21:25:48
	(b) (4)	

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 01:46:55
User entered 'mRNA-1273 (mRNA-1273)'	Peggy Kettle (b) (4) (b) (4)	11 Jan 2021 21:25:48

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	11 Jan 2021 21:25:48

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Jan 2021 21:25:48

US3532002

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

Form: Unblinding

Generated On: 10 Jun 2021 08:06:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered empty.	System	11 Jan 2021 21:25:48

US3532002

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Peggy Kettle (b) (4)	11 Jan 2021 21:26:21

US3532002

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Jan 2021'	Peggy Kettle (b) (4)	11 Jan 2021 21:26:21

US3532002

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '15:40'	Peggy Kettle (b) (4)	11 Jan 2021 21:26:21

US3532002

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:06:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '11 Jan 2021 15:40'	System	11 Jan 2021 21:26:21

US3532002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	(b) (4) Peggy Kettle (b) (4) (b) (4)	11 Jan 2021 21:26:34

US3532002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '11 Jan 2021'	(b) (4) Peggy Kettle (b) (4) (b) (4)	11 Jan 2021 21:26:34

US3532002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:59

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '15:21'	(b) (4) Peggy Kettle (b) (4) (b) (4)	11 Jan 2021 21:26:34

US3532002

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:06:59

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:28:54
User entered '11 Jan 2021 15:21'	System	11 Jan 2021 21:26:34

US3532002

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:06:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:15
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	14 Aug 2020 14:04:40

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 08:58:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 08:58:40
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 19:02:21
User entered 'Worsening Back Pain'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 18:36:55
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	08 Sep 2020 12:49:08
User entered '20 Aug 2020'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User entered empty.	System	01 Sep 2020 19:01:37

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Etza Peters (b) (4)	08 Sep 2020 12:27:36
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

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Generated On: 10 Jun 2021 08:06:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '5 Sep 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Sep 2020 12:27:36
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User entered empty.	System	01 Sep 2020 19:01:37

US3532002

Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 11:56:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 11:56:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Etza Peters (b) (4)	03 Sep 2020 11:56:47
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:01:37
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 11:56:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 11:56:47
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	03 Sep 2020 11:56:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:01:37
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 11:56:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 11:56:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	03 Sep 2020 11:56:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:01:37
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 11:56:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 11:56:47
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	03 Sep 2020 11:56:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:01:37
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 11:56:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 11:56:47
User entered 'None (NONE)' reason for change: Data Entry Error	Etza Peters (b) (4)	03 Sep 2020 11:56:47
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:01:37
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'I'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Etza Peters (b) (4)	08 Sep 2020 12:27:36
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

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 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 19:01:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User entered '0'	System	03 Sep 2020 11:56:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:06:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33
User entered '0'	System	01 Sep 2020 19:01:37

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:41:13
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 12:31:29
User entered	System	23 Sep 2020 12:31:18
'USA-US077-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 12:31:18

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:41:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:42:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:42:53
Data point term sent to Coder	System	15 Sep 2020 23:42:13
User entered 'Worsening Back Pain'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:41:21
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:41:24
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:41:26
User entered 'No (N)'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:41:29
User entered '8 Sep 2020'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:41:32
User closed query 'Per CDM: As per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 09:39:53
Query 'Per CDM: As per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.'	Etza Peters (b) (4)	22 Sep 2020 21:05:03
answered with 'unknown' (Site from DM).	(b) (4)	
User opened query 'Per CDM: As per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 07:28:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:28:03
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Etza Peters (b) (4)	15 Sep 2020 23:42:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	15 Sep 2020 23:41:17
User entered empty.	Etza Peters (b) (4)	15 Sep 2020 23:41:17
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 23:41:17

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:41:37
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	02 Nov 2020 21:13:25
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:41:59
User entered '14 Oct 2020' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	02 Nov 2020 21:13:25
User entered empty.	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 06:46:35
Query 'Data is required. Please provide.' answered with 'unknown' (Site from System).	Etza Peters (b) (4) (b) (4)	02 Nov 2020 21:13:51
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Nov 2020 21:13:25
User entered empty.	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

US3532002

Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 14:36:47
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:35:36
User entered empty.	System	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:02
User entered 'Grade 4 (Grade 4)' reason for change:	Etza Peters (b) (4)	22 Sep 2020 22:20:20
Data Entry Error	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Etza Peters (b) (4)	15 Sep 2020 23:41:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:42:11
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:10
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:42:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 21:07:27
User entered 'No (N)'	Etza Peters (b) (4)	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:20
User entered '0'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:23
User entered '0'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:26
User entered '1' reason for change: Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 21:07:27
User entered '0'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:31
User entered '16 Sep 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 21:07:27
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:33
User entered '18 Sep 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 21:07:27
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:36
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	22 Sep 2020 21:07:27
User entered empty.	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:38
User entered empty.	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:41
User entered '0'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:42:44
User entered '0'	Etza Peters (b) (4)	15 Sep 2020 23:41:17
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:46
User entered '0'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:48
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 23:43:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 23:43:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:43:00
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 23:41:17
User entered empty.	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:50
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 23:43:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 23:43:00
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:43:00
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 23:41:17
User entered empty.	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:42:57
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 23:43:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 23:43:00
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:43:00
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 23:41:17
User entered empty.	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:43:01
User entered '0'	Etza Peters (b) (4)	15 Sep 2020 23:41:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:43:02
User entered 'I'	Etza Peters (b) (4)	15 Sep 2020 23:41:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:43:04
User entered '1' reason for change: Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 21:07:27
User entered '0'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 17:43:07
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 13:15:56
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Etza Peters (b) (4)	02 Nov 2020 21:13:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	02 Nov 2020 21:13:25
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Kathy Stephens (b) (4)	28 Oct 2020 21:38:37
Data Entry Error	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 20:10:51
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 15:48:51
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'still ongoing' (Site from Safety).	Etza Peters (b) (4)	13 Oct 2020 15:19:53
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:22
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Etza Peters (b) (4)	15 Sep 2020 23:41:17
	(b) (4)	

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EAB) (1725)

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[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 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:43:10
User entered empty.	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:41:17

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:43:12
User closed query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. Please leave query open until information was received.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 13:15:58
Query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. Please leave query open until information was received.' answered with 'did not see evidence of covid test in med records' (Site from Safety).	Etza Peters (b) (4) (b) (4)	02 Nov 2020 21:12:56
User opened query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results. Please leave query open until information was received.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 13:13:48
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)	26 Oct 2020 15:10:28
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Hospital Discharge summary sent on 23OCT2020' (Site from Safety).	Etza Peters (b) (4) (b) (4)	25 Oct 2020 19:51:11
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 21:56:41
User closed query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 21:56:38

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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 relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 21:56:33
User closed query 'PV Query: Please confirm date of transforaminal lumbar interbody fusion.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 21:56:30
Query 'PV Query: Please confirm date of transforaminal lumbar interbody fusion.' answered with 'Waiting for med records to be sent' (Site from Safety).	Etza Peters (b) (4) (b) (4)	20 Oct 2020 16:52:06
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Waiting for med records to be sent' (Site from Safety).	Etza Peters (b) (4) (b) (4)	20 Oct 2020 16:52:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Waiting for med records to be sent' (Site from Safety).	Etza Peters (b) (4) (b) (4)	20 Oct 2020 16:51:58
Query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results.' answered with 'waiting for med records to be sent' (Site from Safety).	Etza Peters (b) (4) (b) (4)	20 Oct 2020 16:51:40
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)	02 Oct 2020 15:40:26
User opened query 'PV Query: Please confirm date of transforaminal lumbar interbody fusion.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:48

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:37:36
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)	02 Oct 2020 15:35:55
User opened query 'PV Query: Was the subject tested for COVID-19 while hospitalized? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 15:35:19
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 22:09:18
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Sep 2020 22:09:18
User entered 'Due to underlying back problems and unrelated to vaccine. He had a transforaminal lumbar interbody fusion of his spine due to degenerative disk disease in his back (an underlying medical history problem). Hospitalized after surgery.' reason for change: Data Entry Error	Etza Peters (b) (4)	22 Sep 2020 22:09:18
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 21:07:27
User entered empty.	Etza Peters (b) (4)	15 Sep 2020 23:41:17

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 21:07:27
User entered '0'	System	15 Sep 2020 23:41:17

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 23:41:17

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 21:07:27

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 05:34:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 05:34:52
	(b) (4)	
Data point term sent to Coder	System	10 Dec 2020 17:19:29
User entered 'Worsening Rosacea'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Dec 2020 21:29:37
User entered '15 Nov 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Dec 2020 21:29:37
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Dec 2020 21:29:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Dec 2020 21:29:20
User entered 'UN Nov 2020' (non-conformant).	Etza Peters (b) (4)	11 Dec 2020 21:29:20
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Dec 2020 17:18:53
User entered 'un 2020' (non-conformant).	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User entered empty.	System	10 Dec 2020 17:18:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	25 Jan 2021 13:47:24
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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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 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	25 Jan 2021 13:47:24
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User entered empty.	System	10 Dec 2020 17:18:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 21:29:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 21:29:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Etza Peters (b) (4)	11 Dec 2020 21:29:20
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 17:18:53
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 21:29:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 21:29:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Dec 2020 21:29:20
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 17:18:53
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 21:29:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 21:29:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Dec 2020 21:29:20
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 17:18:53
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 17:31:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 17:31:18
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Etza Peters (b) (4)	10 Dec 2020 17:31:18
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 17:18:53
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'I'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Etza Peters (b) (4)	25 Jan 2021 13:47:24
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

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 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Not related. Underlying medical problem that is worse.' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Dec 2020 21:30:16
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:18:53
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User entered '0'	System	10 Dec 2020 17:18:53

US3532002

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38
User entered '1'	System	10 Dec 2020 17:18:53

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:38

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 14:18:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 14:18:40
	(b) (4)	
Data point term sent to Coder	System	06 Jan 2021 14:18:26
User entered 'Squamous Cell Carcinoma'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '8 Dec 2020'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User entered empty.	System	06 Jan 2021 14:17:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(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	08 Jan 2021 14:12:31
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	08 Jan 2021 14:12:31
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	06 Jan 2021 14:17:43
User entered '29 Dec 2020'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User entered empty.	System	06 Jan 2021 14:17:43

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 14:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 14:12:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Etza Peters (b) (4)	08 Jan 2021 14:12:08
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 14:17:43
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 14:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 14:12:08
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Jan 2021 14:12:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 14:17:43
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 14:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 14:12:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Jan 2021 14:12:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 14:17:43
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 14:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 14:12:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Jan 2021 14:12:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 14:17:43
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 14:12:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 14:12:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Etza Peters (b) (4)	08 Jan 2021 14:12:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 14:17:43
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 06:26:28
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Updated' (Site from DM).	Etza Peters (b) (4)	12 Feb 2021 21:10:52
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 22:57:19
User entered 'I'	Etza Peters (b) (4)	06 Jan 2021 14:17:43

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Etza Peters (b) (4)	08 Jan 2021 14:12:31
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

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 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	06 Jan 2021 14:17:43
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User entered '0'	System	08 Jan 2021 14:12:08

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42
User entered '1'	System	06 Jan 2021 14:17:43

US3532002

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:55:42

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Mar 2021 21:43:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 21:43:43
Data point term sent to Coder	System	09 Mar 2021 21:42:36
User entered 'Worsening hypertension'	Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:41:51

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Yes (Y)'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '12 Feb 2021'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 21:41:51

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Yes (Y)'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 21:41:51

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 20:17:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 20:17:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	10 Mar 2021 20:17:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 21:41:51
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 20:17:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 20:17:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	10 Mar 2021 20:17:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 21:41:51
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'I'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:41:51

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[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 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:41:51
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
User entered 'Physician increased carvedilol currently taken for hypertension.'	(b) (4) Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:41:51

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 21:41:51

US3532002

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:06:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 21:41:51

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Mar 2021 21:45:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 21:45:40
Data point term sent to Coder	System	09 Mar 2021 21:44:44
User entered 'worsening hypothyroidism'	Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:43:44

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Yes (Y)'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '12 Feb 2021'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 21:43:44

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Yes (Y)'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 21:43:44

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 20:17:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 20:17:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	10 Mar 2021 20:17:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 21:43:44
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Mar 2021 20:17:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 20:17:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Etza Peters (b) (4)	10 Mar 2021 20:17:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 21:43:44
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:43:44

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

None

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Mar 2021 20:17:52
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Mar 2021 21:43:44
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Etza Peters (b) (4)	10 Mar 2021 20:17:52
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:43:44

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[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 09:04:55
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:43:44
	(b) (4)	

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:04:55
User entered 'Physician increased levothyroxine which he is currently taking for hypothyroidism.'	(b) (4) Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:43:44

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 21:43:44

US3532002

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:06:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Mar 2021 21:43:44

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:15
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:35:36
Query 'D/C summary = Prednisone 20 mg daily x 3 days, please verify' canceled (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:35:34
User opened query 'D/C summary = Prednisone 20 mg daily x 3 days, please verify' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:09:38
Query 'D/S summary indicates subject to continue Prednisone, 20 mg daily x 3 days. Please verify' canceled (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:09:13
User opened query 'D/S summary indicates subject to continue Prednisone, 20 mg daily x 3 days. Please verify' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:09:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:28:11

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 21:41:17
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 Aug 2020 21:41:17
Data point term sent to Coder Coding entries removed.	System Etza Peters (b) (4) (b) (4)	14 Aug 2020 19:06:13 14 Aug 2020 19:06:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:20:12
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 Aug 2020 00:20:12
Data point term sent to Coder User entered 'Fenofibrate'	System Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:30:19 11 Aug 2020 23:29:49

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'ELEVATED CHOLESTERoL' reason for change: Data Entry Error	Etza Peters (b) (4)	14 Aug 2020 19:06:08
	(b) (4)	
User entered 'Elevated Cholesteral'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '145'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'mg (mg)'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'once daily (QD)'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'I'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:29:49
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:29:49

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:29:49

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 23:29:49

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 23:33:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:33:17
Data point term sent to Coder	System	11 Aug 2020 23:32:25
User entered 'Carvedilol'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Hypertension'	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '6.25'	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'mg (mg)'	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'twice daily (BID)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'I'	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
Signature has been broken.	Etza Peters (b) (4)	26 Mar 2021 19:51:47
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	26 Mar 2021 19:51:47
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	26 Mar 2021 19:51:47
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Mar 2021 21:46:11
Signature has been broken.	Teresa Ball (b) (4)	09 Mar 2021 21:46:11
User entered '12 Feb 2021' reason for change: New Information	(b) (4)	
User signature succeeded.	Teresa Ball (b) (4)	09 Mar 2021 21:46:11
	(b) (4)	
User entered empty.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
	Etza Peters (b) (4)	11 Aug 2020 23:32:25
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User entered '2'	System	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User entered '1'	System	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:14
User entered '804 (804)'	System	11 Aug 2020 23:32:25

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 23:34:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:34:16
Data point term sent to Coder	System	11 Aug 2020 23:33:26
User entered 'Amlodipine'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:33:23

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Hypertension'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '10'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'mg (mg)'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'once daily (QD)'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'I'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:33:23
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:33:23

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:33:23

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 23:33:23

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 23:35:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:35:17
Data point term sent to Coder	System	11 Aug 2020 23:34:27
User entered 'Losartan'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:33:54

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Hypertension'	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '100'	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'mg (mg)'	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'once daily (QD)'	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'I'	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 23:50:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 23:50:04
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4)	11 Aug 2020 23:50:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 23:33:54
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:33:54
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:33:54

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:33:54

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 23:33:54

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 23:08:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:08:40
Data point term sent to Coder Coding entries removed.	System Etza Peters (b) (4)	22 Sep 2020 22:17:44 22 Sep 2020 22:17:29
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: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 10:35:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 10:35:21
Data point term sent to Coder User entered 'Baby Aspirin'	System Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:36:32 11 Aug 2020 23:35:38

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please review if this is related to MH=HYPERTENSION . If so, update indication so there is an appropriate match with MH condition. Else, confirm if used for heart health and update prophylaxis field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 09:55:10
Query 'Per DM CLR: Please review if this is related to MH=HYPERTENSION . If so, update indication so there is an appropriate match with MH condition. Else, confirm if used for heart health and update prophylaxis field. ' answered with 'ok' (Site from DM).	Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:17:33
User entered 'GENERAL Heart HEALTH' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:17:29
User opened query 'Per DM CLR: Please review if this is related to MH=HYPERTENSION . If so, update indication so there is an appropriate match with MH condition. Else, confirm if used for heart health and update prophylaxis field. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:14:01
User entered 'General Health'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:35:38

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '81'	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'mg (mg)'	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'once daily (QD)'	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 10:54:31
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing' (Site from System).	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:50:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 23:35:38
User entered 'un UNK 2016'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:35:38

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:35:38
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:35:38

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:35:38

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 23:35:38

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 20:44:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 20:44:46
Data point term sent to Coder Coding entries removed.	System Etza Peters (b) (4) (b) (4)	14 Aug 2020 19:07:18 14 Aug 2020 19:06:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:37:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:37:19
Data point term sent to Coder User entered 'Rosuvastatin'	System Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:38:34 11 Aug 2020 23:37:43

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'ELEVATED CHOLESTERoL' reason for change: Data Entry Error	Etza Peters (b) (4)	14 Aug 2020 19:06:40
	(b) (4)	
User entered 'Elevated Cholesteral'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '20'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'mg (mg)'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'once daily (QD)'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'I'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:37:43
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:37:43

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:37:43

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 23:37:43

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 23:40:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:40:22
Data point term sent to Coder	System	11 Aug 2020 23:39:36
User entered 'Ozempic'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:38:59

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Type 2 Diabetes'	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 09:58:43
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' answered with 'reviewed' (Site from DM).	Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:16:15
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:17:42
User entered '5'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:38:59

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'mg (mg)'	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'every week (QS)' reason for change:	Etza Peters (b) (4)	28 Aug 2020 14:44:40
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per CDM: Every week option is available at drop down at frequency field. Please verify and consider to update CRF else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:50:16
Query 'Per CDM: Every week option is available at drop down at frequency field. Please verify and consider to update CRF else clarify.' answered with 'updated' (Site from DM).	Etza Peters (b) (4) (b) (4)	28 Aug 2020 14:44:50
User entered empty; reason for change Data Entry Error	Etza Peters (b) (4) (b) (4)	28 Aug 2020 14:44:40
User opened query 'Per CDM: Every week option is available at drop down at frequency field. Please verify and consider to update CRF else clarify.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 11:32:31
User entered 'weekly'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:38:59

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:38:59

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 10:54:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing' (Site from System).	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:51:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 23:38:59
User entered 'un UNK 2019'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:38:59

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:38:59
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:44:40
User entered empty.	System	11 Aug 2020 23:38:59

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 14:44:40
User entered empty.	System	11 Aug 2020 23:38:59

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	28 Aug 2020 14:44:40
User entered empty.	System	11 Aug 2020 23:38:59

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 23:41:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 23:41:16
Data point term sent to Coder	System	11 Aug 2020 23:40:38
User entered 'Metformin'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Type 2 Diabetes'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '750'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'mg (mg)'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'twice daily (BID)'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 10:54:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing' (Site from System).	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:51:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 23:40:22
User entered 'un UNK 2016'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:40:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'Yes (Y)'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:40:22
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 23:40:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 23:40:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 23:40:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 23:42:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 23:42:16
Data point term sent to Coder	System	11 Aug 2020 23:41:42
User entered 'Levothyroxine'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Hypothyroidism'	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '50'	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 17:37:47
User entered 'Other (OTHER)'	Etza Peters (b) (4)	11 Aug 2020 23:41:27
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty; reason for change Data Entry Error	(b) (4) Etza Peters (b) (4)	21 Oct 2020 17:37:47
User entered 'mcg'	(b) (4) Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'once daily (QD)'	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 10:55:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing' (Site from System).	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:52:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 23:41:27
User entered 'un UNK 1985'	Etza Peters (b) (4) (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
Signature has been broken.	(b) (4) Teresa Ball (b) (4)	09 Mar 2021 21:53:23
User entered 'No (N)' reason for change: New Information	(b) (4) Teresa Ball (b) (4)	09 Mar 2021 21:53:23
User signature succeeded.	(b) (4) Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	(b) (4) Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	09 Mar 2021 21:53:23
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Mar 2021 21:45:04
Signature has been broken.	Teresa Ball (b) (4)	09 Mar 2021 21:45:04
User entered '12 Feb 2021' reason for change: New Information	(b) (4)	09 Mar 2021 21:45:04
User signature succeeded.	Teresa Ball (b) (4)	09 Mar 2021 21:45:04
User entered empty.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
	Etza Peters (b) (4)	11 Aug 2020 23:41:27
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User entered '1'	System	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User entered '1'	System	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:31
User entered '804 (804)'	System	11 Aug 2020 23:41:27

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
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, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Sep 2020 23:46:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:46:50
Data point term sent to Coder	System	15 Sep 2020 23:45:16
User entered 'Advil'	Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Headache'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'unknown'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'mg (mg)'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'once (ONCE)'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Oral (ORAL)'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '10 Sep 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '10 Sep 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 20:46:03
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 04:03:38
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.	Lisa Macoy (b) (4) (b) (4)	12 Oct 2020 18:22:17
' answered with 'did not meet AE reporting' (Site from DM).		

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Etza Peters (b) (4) (b) (4)	02 Oct 2020 11:59:42 15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
User entered empty.	System	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
User entered empty.	System	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:48
User entered empty.	System	15 Sep 2020 23:44:22

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Sep 2020 03:20:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 03:20:35
Data point term sent to Coder	System	01 Sep 2020 18:57:07
User entered 'methocarbamol'	Etza Peters (b) (4) (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Worsening back pain'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '500'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'mg (mg)'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'as needed (PRN)'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'un Aug 2020'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 21:26:49
User entered 'Yes (Y)'	Etza Peters (b) (4)	01 Sep 2020 18:56:26
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '14 Oct 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	02 Nov 2020 21:26:49
User entered empty.	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User entered empty.	System	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User entered empty.	System	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:10:59
User entered empty.	System	01 Sep 2020 18:56:26

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:04:32
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Sep 2020 09:42:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 09:42:46
Data point term sent to Coder	System	22 Sep 2020 22:15:35
User entered 'Percocet'	Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:04:34
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:04:47
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Worsening Back Pain'	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:04:53
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please provide the dosage for this combination medication as there are many dosage options for this drug (e.g., 5/325 mg, 10/325 mg, etc). Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 07:48:52
Query 'Per DM CLR: Please provide the dosage for this combination medication as there are many dosage options for this drug (e.g., 5/325 mg, 10/325 mg, etc). Update ConMed eCRF as appropriate. ' answered with 'updated' (Site from DM).	Etza Peters (b) (4) (b) (4)	23 Oct 2020 17:26:28
User entered '10/325' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	23 Oct 2020 17:26:00
User opened query 'Per DM CLR: Please provide the dosage for this combination medication as there are many dosage options for this drug (e.g., 5/325 mg, 10/325 mg, etc). Update ConMed eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 06:51:22
User entered 'I'	Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:04:54
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	
	Etza Peters (b) (4)	23 Oct 2020 17:26:00
User entered 'tablet (TABLET)'	(b) (4)	
	Etza Peters (b) (4)	22 Sep 2020 22:15:17
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:04:57
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'other (OTHER)'	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:15
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Every 6 hours'	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Oral (ORAL)'	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:19
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:22
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '17 Sep 2020'	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:24
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:27
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 04:43:42
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Etza Peters (b) (4) (b) (4)	25 Jan 2021 13:50:14
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	25 Jan 2021 13:50:05
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:38:18
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:30
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '29 Sep 2020' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 13:50:05
User entered empty.	Etza Peters (b) (4)	22 Sep 2020 22:15:17
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:05:32
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
User entered empty.	System	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
User entered empty.	System	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:11:18
User entered empty.	System	22 Sep 2020 22:15:17

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 13:41:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 13:41:20
Data point term sent to Coder	System	02 Nov 2020 21:18:08
Coding entries removed.	Etza Peters (b) (4)	02 Nov 2020 21:17:35
Coding entries removed.	Etza Peters (b) (4)	02 Nov 2020 21:17:35
User entered 'INFLUENZA VACCINE' reason for change: Data Entry Error	Etza Peters (b) (4)	02 Nov 2020 21:17:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 21:20:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 21:20:27
Data point term sent to Coder	System	12 Oct 2020 18:21:55
User entered 'high dose influenza vaccine'	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Annual Vaccine' reason for change:	(b) (4)	
Data Entry Error	Etza Peters (b) (4)	02 Nov 2020 21:17:35
User entered 'influenza'	(b) (4)	
	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'unknown' reason for change: Data Entry Error	(b) (4)	02 Nov 2020 21:17:35
User entered '0.5'	Etza Peters (b) (4)	12 Oct 2020 18:21:24
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Etza Peters (b) (4)	02 Nov 2020 21:17:35
User entered 'mL (mL)'	(b) (4)	
	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	(b) (4) System	02 Nov 2020 21:17:43
User entered 'unknown' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	02 Nov 2020 21:17:43
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	02 Nov 2020 21:17:35
User entered empty.	Lisa Macoy (b) (4) (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'once (ONCE)'	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Intramuscular (INTRAMUSCULAR)'	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '10 Nov 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	10 Dec 2020 17:15:09
User entered '16 Oct 2020' reason for change: Data Entry Error	Etza Peters (b) (4)	02 Nov 2020 21:17:35
User entered '8 Oct 2020'	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Etza Peters (b) (4)	10 Dec 2020 17:15:09
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Etza Peters (b) (4)	02 Nov 2020 21:17:35
User entered '8 Oct 2020'	(b) (4)	
	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Lisa Macoy (b) (4)	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User entered empty.	System	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User entered empty.	System	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:00
User entered empty.	System	12 Oct 2020 18:21:24

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Dec 2020 19:06:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:06:59
Data point term sent to Coder	System	10 Dec 2020 17:17:28
User entered 'Doxycycline'	Etza Peters (b) (4) (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
Un-reviewed for Data Management.	(b) (4), (b) (6)	06 Apr 2021 11:20:34
Reviewed for Data Management.	(b) (4), (b) (6)	06 Apr 2021 11:20:29
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	(b) (4) Etza Peters (b) (4) (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Worsening Rosacea'	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '50'	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'mg (mg)'	(b) (4) Etza Peters (b) (4) (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'once daily (QD)'	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Oral (ORAL)'	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '8 Dec 2020'	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '0'	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 09:13:37
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Subject took a 30 day supply before stopping' (Site from DM).	Etza Peters (b) (4) (b) (4)	26 Mar 2021 20:01:05
Signature has been broken.	Etza Peters (b) (4) (b) (4)	26 Mar 2021 20:00:41
User entered 'No (N)' reason for change: Data Entry Error	Etza Peters (b) (4) (b) (4)	26 Mar 2021 20:00:41
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 01:08:40
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)'	Etza Peters (b) (4) (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/top dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 02:29:53
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/top dates as appropriate.' answered with 'Subject was prescribed the medication for a month but worsening symptoms had resolved by the15DEC.' (Site from DM).	Etza Peters (b) (4)	06 Apr 2021 19:43:48
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/top dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:20:39
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
Signature has been broken.	Etza Peters (b) (4)	26 Mar 2021 20:00:41
User entered '07 Jan 2021' reason for change: Data Entry Error	Etza Peters (b) (4)	26 Mar 2021 20:00:41
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'No (N)'	Etza Peters (b) (4)	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User entered '1'	System	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User entered '1'	System	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:10
User entered '804 (804)'	System	10 Dec 2020 17:16:58

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Mar 2021 11:25:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 11:25:49
Data point term sent to Coder	System	09 Mar 2021 21:48:46
User entered 'carvedilol'	Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:48:14

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'Worsening Hypertension'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered '12.5'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'mg (mg)'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'twice daily (BID)'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered '12 Feb 2021'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'Yes (Y)'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:48:14
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Mar 2021 21:48:14

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 21:48:14

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 21:48:14

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Mar 2021 21:50:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 21:50:40
Data point term sent to Coder	System	09 Mar 2021 21:49:50
User entered 'Levothyroxine'	Teresa Ball (b) (4) (b) (4)	09 Mar 2021 21:49:39

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'worsening hypothyroidism'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered '75'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'Other (OTHER)'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'Mcg'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'once daily (QD)'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

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

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered '12 Feb 2021'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered '0'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'Yes (Y)'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered empty.	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
	(b) (4)	
User entered 'No (N)'	Teresa Ball (b) (4)	09 Mar 2021 21:49:39
	(b) (4)	

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 21:49:39

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 21:49:39

US3532002

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:06:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 21:49:39

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:06:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:41:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:07:04
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 21:03:27
User entered 'No (N)'	Etza Peters (b) (4)	11 Aug 2020 23:27:52
	(b) (4)	

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:06:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:59:21
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '16 Sep 2020'	Etza Peters (b) (4)	22 Sep 2020 21:04:29

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:06:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:59:23
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Transforaminal lumbar interbody fusion'	Etza Peters (b) (4)	22 Sep 2020 21:04:29

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:59:25
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Adverse Event (AE)'	Etza Peters (b) (4)	22 Sep 2020 21:04:29

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:06:59

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:59:27
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered empty.	Etza Peters (b) (4)	22 Sep 2020 21:04:29

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:06:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:22:21
User closed query 'per D/C summary surgery was 16Sep2020, please verify' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:20:10
Query 'per D/C summary surgery was 16Sep2020, please verify' answered with 'Subject continued to have PT related after his back surgery' (Site from CRA).	Etza Peters (b) (4)	26 Mar 2021 19:56:19
User opened query 'per D/C summary surgery was 16Sep2020, please verify' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 18:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:00:53
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:59:39
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '10 Nov 2020'	Etza Peters (b) (4)	10 Dec 2020 17:12:08

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:06:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:17
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Reoccurring PHYSICAL THERAPY'	(b) (4)	
reason for change: Data Entry Error	Etza Peters (b) (4)	10 Dec 2020 17:12:36
User entered 'Physical Therapy'	(b) (4)	
	Etza Peters (b) (4)	10 Dec 2020 17:12:08
	(b) (4)	

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:18
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Other (OTHER)'	(b) (4) Etza Peters (b) (4) (b) (4)	10 Dec 2020 17:12:08

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:06:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:33
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:15:21
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'Related to recent back surgery'	(b) (4) Etza Peters (b) (4) (b) (4)	10 Dec 2020 17:12:08

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:06:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered '29 Dec 2020'	Etza Peters (b) (4)	12 Feb 2021 21:12:57

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:06:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered 'Squamous Cell Removal'	Etza Peters (b) (4)	12 Feb 2021 21:12:57

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:06:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered 'Adverse Event (AE)'	Etza Peters (b) (4)	12 Feb 2021 21:12:57

US3532002

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:06:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:36
User signature succeeded.	Evan Anderson (b) (4)	02 Apr 2021 18:42:30
User entered empty.	Etza Peters (b) (4)	12 Feb 2021 21:12:57

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'USA-US077-2020-MRNA-1273-P301000003'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Evan'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Anderson'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '2015 Uppergate Drive'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Atlanta'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'GA'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '30323'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:12:24
User entered 'US'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '5'	System	03 Nov 2020 13:16:14
User entered '4'	System	29 Oct 2020 19:04:14
User entered '3'	System	26 Oct 2020 15:12:34
User entered '2'	System	21 Oct 2020 21:45:59
User entered '1'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'USA-US077-2020-MRNA-1273-P301000003'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Evan'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Anderson'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '2015 Uppergate Drive'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Atlanta'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'GA'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '30323'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:12:24
User entered 'US'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '5'	System	03 Nov 2020 13:16:14
User entered '4'	System	29 Oct 2020 19:04:14
User entered '3'	System	26 Oct 2020 15:12:34
User entered '2'	System	21 Oct 2020 21:45:59
User entered '1'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:06:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '23/Sep/2020 08:32'	(b) (4) System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:12:24
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'USA-US077-2020-MRNA-1273-P301000003'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Evan'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Anderson'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '2015 Uppergate Drive'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Atlanta'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'GA'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '30323'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:12:24
User entered 'US'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '5'	System	03 Nov 2020 13:16:14
User entered '4'	System	29 Oct 2020 19:04:14
User entered '3'	System	26 Oct 2020 15:12:34
User entered '2'	System	21 Oct 2020 21:45:59
User entered '1'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:06:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '21/Oct/2020 17:45'	(b) (4) System	21 Oct 2020 21:45:59

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:12:24
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 21:45:59

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'USA-US077-2020-MRNA-1273-P301000003'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Evan'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Anderson'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '2015 Uppergate Drive'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Atlanta'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'GA'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '30323'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:12:24
User entered 'US'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '5'	System	03 Nov 2020 13:16:14
User entered '4'	System	29 Oct 2020 19:04:14
User entered '3'	System	26 Oct 2020 15:12:34
User entered '2'	System	21 Oct 2020 21:45:59
User entered '1'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:06:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '26/Oct/2020 15:12'	(b) (4) System	26 Oct 2020 15:12:34

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:04:02
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 15:12:34

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'USA-US077-2020-MRNA-1273-P301000003'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Evan'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Anderson'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '2015 Uppergate Drive'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Atlanta'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'GA'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '30323'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:12:24
User entered 'US'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '5'	System	03 Nov 2020 13:16:14
User entered '4'	System	29 Oct 2020 19:04:14
User entered '3'	System	26 Oct 2020 15:12:34
User entered '2'	System	21 Oct 2020 21:45:59
User entered '1'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:06:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '29/Oct/2020 19:04'	(b) (4) System	29 Oct 2020 19:04:14

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:16:06
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 19:04:14

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'USA-US077-2020-MRNA-1273-P301000003'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Yes (Y)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'No (N)'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Evan'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Anderson'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '2015 Uppergate Drive'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'Atlanta'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered 'GA'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:32:12
User entered '30323'	System	23 Sep 2020 12:31:18

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:12:24
User entered 'US'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 08:06:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
	(b) (4)	
User entered '5'	System	03 Nov 2020 13:16:14
User entered '4'	System	29 Oct 2020 19:04:14
User entered '3'	System	26 Oct 2020 15:12:34
User entered '2'	System	21 Oct 2020 21:45:59
User entered '1'	System	23 Sep 2020 12:32:22

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:06:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered '03/Nov/2020 08:16'	(b) (4) System	03 Nov 2020 13:16:14

US3532002

Folder: SAE USA-US077-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:06:59

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)	04 Mar 2021 17:58:46
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 19:58:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 13:16:14