

US3532276 (Prod: Children's Healthcare of Atlanta)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:08:32

All time stamps listed in this document are displayed in GMT

US3532276

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 03:59:56

Generated On: 10 Jun 2021 08:08:32

Participant ID

US3532276

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

US3532276

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 11:09:55

Generated On: 10 Jun 2021 08:08:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3532276

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	77
Age Units	YEARS
Age (Derived)	78
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 11:09:55

Generated On: 10 Jun 2021 08:08:32

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 11:09:55

Generated On: 10 Jun 2021 08:08:32

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	ALLERGY TO SULFA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	ALLERGY TO ANTIFUNGAL DRUGS
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	ALLERGY TO TETANUS SHOT
Start date (dd MMM yyyy)	UN UNK 1945
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 1945
Start Year (derived)	1945
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	MILD INTERMEDIATE ASTHMA
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Start Year (derived)	1981
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3532276

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	CANDIDAL DERMATITIS
Start date (dd MMM yyyy)	UN JUN 2020
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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	RIGHT KNEE TOTAL REPLACEMENT
Start date (dd MMM yyyy)	UN AUG 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2010
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2010
Start Year (derived)	2010
Stop Month and Year (derived)	AUG 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1944
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 1944
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1944
Start Year (derived)	1944
Stop Month and Year (derived)	JAN 1944
Stop Year (derived)	1944

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	LEFT KNEE TENDON REPAIR
Start date (dd MMM yyyy)	UN UNK 1961
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 1961
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1961
Start Year (derived)	1961
Stop Month and Year (derived)	JAN 1961
Stop Year (derived)	1961

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	RIGHT KNEE LATERAL RELEASE
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	RUPUTRED ACHILLES TENDON
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	RIGHT ANKLE SURGERY
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	JAN 1993
Stop Year (derived)	1993

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	LEFT ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN MAR 2017
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 MAR 2017
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAR 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1945
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 1945
Start Year (derived)	1945
Stop Month and Year (derived)	
Stop Year (derived)	

US3532276

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 16 Apr 2021 16:09:26

Generated On: 10 Jun 2021 08:08:32

Condition	ECZEMA
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)	

US3532276

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 11:09:55

Generated On: 10 Jun 2021 08:08:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:20 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:20
Height (<i>xxx.x</i>)	157.4 cm
Weight (<i>xxx.x</i>)	82 kg
BMI (<i>xxx.x</i>)	33.09820 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)	

US3532276

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 11:09:55

Generated On: 10 Jun 2021 08:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Date of assessment (dd MMM yyyy) 10 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 1981

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 11:09:55

Generated On: 10 Jun 2021 08:08:32

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 RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 11:09:55

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

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

What was the participant's randomization number? 190536

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Height	ND - Not Done
Weight	ND - Not Done

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:20
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	12:14 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:14
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3532276

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 11:41 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 11:41

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

US3532276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	11:26 (24 HR)
Collection date and time (derived)	10 SEP 2020 11:26

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:18	10 SEP 2020 11:18
Nasopharyngeal Swab 2	No		

US3532276

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:19

PC Open Date & Time

10 SEP 2020 12:01

PC Close Date & Time

10 SEP 2020 14:31

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

PC Time Stamp	10 SEP 2020 22:44
PC Open Date & Time	10 SEP 2020 15:26
PC Close Date & Time	11 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 06:12

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 13:22

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:27

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 16:58

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 17:08

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 16:29

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 12:20

PC Open Date & Time

10 SEP 2020 12:01

PC Close Date & Time

10 SEP 2020 14:31

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 22:44

PC Open Date & Time

10 SEP 2020 15:26

PC Close Date & Time

11 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 06:13

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 13:23

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 19:28

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 16:58

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 17:08

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 16:29

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 12:21
PC Open Date & Time	10 SEP 2020 12:01
PC Close Date & Time	10 SEP 2020 14:31

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 22:45
PC Open Date & Time	10 SEP 2020 15:26
PC Close Date & Time	11 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

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 ☒

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 06:13
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 13:24
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

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

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EAB) (1725)

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:28
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

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

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EAB) (1725)

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 16:59
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 17:09
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

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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US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 16:30
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3532276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

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

Visit date (dd MMM yyyy)	8 OCT 2020
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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	VISIT2
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US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

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 OCT 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 09:20
Temperature (xxx.x)	97 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	10:29 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:29
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3532276

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

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 OCT 2020

What was the treatment time? (00:00-23:59) 09:56 (24 HR)

Treatment Date and Time (derived) 8 OCT 2020 09:56

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

US3532276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

09:35 (24 HR)

Collection date and time (derived)

8 OCT 2020 09:35

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:46	8 OCT 2020 09:46
Nasopharyngeal Swab 2	No		

US3532276

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 08 OCT 2020 10:31

PC Open Date & Time 08 OCT 2020 10:16

PC Close Date & Time 08 OCT 2020 12:46

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	08 OCT 2020 17:33
PC Open Date & Time	08 OCT 2020 13:41
PC Close Date & Time	09 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

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

98.2 °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

09 OCT 2020 16:11

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 18:46

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 15:16

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 15:39

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 13:54

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

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

97.6 °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

14 OCT 2020 16:52

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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 OCT 2020 10:31

PC Open Date & Time

08 OCT 2020 10:16

PC Close Date & Time

08 OCT 2020 12:46

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 17:33

PC Open Date & Time

08 OCT 2020 13:41

PC Close Date & Time

09 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 16:11

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 18:47

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 15:16

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

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 OCT 2020 15:39

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

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 OCT 2020 13:54

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

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 OCT 2020 16:52

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 10:32
PC Open Date & Time	08 OCT 2020 10:16
PC Close Date & Time	08 OCT 2020 12:46

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 17:34
PC Open Date & Time	08 OCT 2020 13:41
PC Close Date & Time	09 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

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
EAB) (1725)

116 of 3358

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 18:48
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

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)

118 of 3358

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 15:17
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

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 ☒

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 15:40
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

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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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 13:55
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

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 ☒

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 16:53
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3532276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 11:09:54

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

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

Visit date (dd MMM yyyy)	5 NOV 2020
--------------------------	------------

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

Folder OID	VISIT3
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US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 11:59
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532276

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

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.

US3532276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 NOV 2020

Collection time (00:00-23:59)

12:02 (24 HR)

Collection date and time (derived)

5 NOV 2020 12:02

US3532276

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:29:56

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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	10 NOV 2020 03:20:16
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 07:25:58

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 NOV 2020 07:40:12
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 10:15:11

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 07:37:07
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 07:57:34
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 DEC 2020 11:39:18

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 08:34:35

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

02 JAN 2021 18:13:46

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	09 JAN 2021 16:29:53
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 JAN 2021 08:54:23
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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	23 JAN 2021 08:10:58
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

30 JAN 2021 11:30:39

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

06 FEB 2021 10:24:48

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

13 FEB 2021 07:05:29

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 16:47:14

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

27 FEB 2021 12:29:38

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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	06 MAR 2021 09:11:48
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

13 MAR 2021 08:39:13

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 12:00:52

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

27 MAR 2021 07:20:03

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

03 APR 2021 07:16:15

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

10 APR 2021 07:47:22

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

17 APR 2021 04:07:53

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 09:20:59

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 06:01:12

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 <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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

Patient Cloud Open Date & Time	25 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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="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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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°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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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°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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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="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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 <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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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"/>

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3532276

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:08:32

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 12:29:14

US3532276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:46:02

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:46:02

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 08:28:30

Generated On: 10 Jun 2021 08:08:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 APR 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

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 08:28:30

Generated On: 10 Jun 2021 08:08:32

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) _____

US3532276

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 08:28:30

Generated On: 10 Jun 2021 08:08:32

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.

US3532276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 08:28:30

Generated On: 10 Jun 2021 08:08:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 APR 2021

Collection time (00:00-23:59)

09:58 (24 HR)

Collection date and time (derived)

7 APR 2021 09:58

US3532276

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 08:28:30

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 16:27:16

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 16:27:16

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Date of Contact	19 JAN 2021
Time of Contact	15:00
Date and Time of Contact (derived)	19 JAN 2021 15:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Form: Symptom Log (3)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Symptom Day

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

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 JAN 2021	
Assessment Not Done	False	
O2 Saturation	60 %	
O2 Saturation Units	%	
Temperature	93 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Date of Visit	19 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	19 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 JAN 2021
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	15:10 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 15:10
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3532276

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 JAN 2021

US3532276

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:00:24

Generated On: 10 Jun 2021 08:08:32

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

Visit date (dd MMM yyyy)	6 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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US3532276

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 04:00:24

Generated On: 10 Jun 2021 08:08:32

Date of updated informed consent (<i>dd MMM yyyy</i>)	6 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	6 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3532276

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3532276

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	6 JAN 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 10:55
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3532276

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	6 JAN 2021
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 12:17
Temperature (xxx.x)	97 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3532276

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

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:00:24

Generated On: 10 Jun 2021 08:08:32

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.

US3532276

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

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:00:24

Generated On: 10 Jun 2021 08:08:32

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 6 JAN 2021

What was the treatment time? (00:00-23:59) 11:44 (24 HR)

Treatment Date and Time (derived) 6 JAN 2021 11:44

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

What was the frequency of the study treatment dosing? ONCE

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

US3532276

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:00:24

Generated On: 10 Jun 2021 08:08:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 JAN 2021

Collection time (00:00-23:59)

11:11 (24 HR)

Collection date and time (derived)

6 JAN 2021 11:11

US3532276

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:00:24

Generated On: 10 Jun 2021 08:08:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	11:01
Collection Date and Time (derived)	6 JAN 2021 11:01

US3532276

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

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:00:24

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:00:26

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3532276

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

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)	3 FEB 2021
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 10:34
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

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)	3 FEB 2021
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 12:17
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3532276

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 FEB 2021

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

US3532276

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 FEB 2021

What was the treatment time? (00:00-23:59) 11:45 (24 HR)

Treatment Date and Time (derived) 3 FEB 2021 11:45

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

US3532276

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3532276

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3532276

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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	OLD57

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:53 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 09:53
Temperature (<i>xxx.x</i>)	97.4 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>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3532276

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

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.

US3532276

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 03:59:58

Generated On: 10 Jun 2021 08:08:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00-23:59)	10:00 (24 HR)
Collection date and time (derived)	4 MAR 2021 10:00

US3532276

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 09:18:29

Generated On: 10 Jun 2021 08:08:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

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

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EAB) (1725)

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US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

AEID

Adverse event

BROKEN CROWN ON TOOTH

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)

28 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

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	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)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

AEID

Adverse event

WORSENING LEFT DRY EYE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

01 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)

23 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

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	WORSENING DRY EYES, USING EYE DROPS. SUBJECT TO FOLLOW WITH OPTH
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)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

AEID	
Adverse event	RHINITIS- ALLERGIC
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 OCT 2020
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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

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 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	RUNNY NOSE- CLEAR, STARTED AFTER CLEANING OUT ATTIC, HX OF SEASONAL ALLERGIES
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

AEID

Adverse event

UPPER RESPIRATORY
INFECTION- ETIOLOGY
UNKNOWN

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)

11 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

AEID	USA-US077-2021-MRNA-1273-P30 1000002
Adverse event	ASTHMA EXACERBATION
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)	4 FEB 2021
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	4 FEB 2021 08:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 FEB 2021
End time (00:00-23:59)	08:00 (24 HR)
AE End Date and Time (derived)	10 FEB 2021 08:00
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)	8 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	9 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	NOT RELATED TO VACCINE, DUE TO UNDERLYING ASTHMA EXACERBATION. ADMITTED TO OBSERVATION UNIT ONLY FOR LESS THAN 24HRS, UNCERTAIN IF NEED TO BE AN SAE, BUT WILL REPORT FOR NOW.

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 16:27:15

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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

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

AEID	
Adverse event	ASTHMA EXACERBATION
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)	27 FEB 2021
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)	15 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 16:27:15

Generated On: 10 Jun 2021 08:08:32

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	
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) 03 Apr 2021 03:59:57

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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) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication BIOTIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 44

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) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication CITRUCEL

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication ALBUTEROL HFA

Prophylaxis Yes ☐
No ☒

Indication MILD INTERMEDIATE ASTHMA

Dose per administration 90

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) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

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 (5)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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 NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 20 Apr 2021 15:50:26

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

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 (7)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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 2005	
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 (8)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication PREMARIN

Prophylaxis Yes ☐
No ☒

Indication HYSTERECTOMY

Dose per administration 0.3

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 (8)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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 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 (9)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication KETACONAZOLE

Prophylaxis Yes ☐
No ☒

Indication CANDID DERMATITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication PROBIOTIC

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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 (11)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication RIGHT KNEE TOTAL REPLACEMENT

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication B12

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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 (15)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

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 (15)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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 (16)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication AMOXICILLIN

Prophylaxis Yes ☒
No ☐

Indication DENTAL PROCEDURES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication AMOXILCILLIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR DENTAL PROCEDURES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication SYSTANE EYE DROPS
[POLYETHYLENE GLYCOL 400
AND PROPYLENE GLYCOL]

Prophylaxis Yes ☐
No ☒

Indication DRY EYE LEFT

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUNENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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)	17 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)		17 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

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 (20)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication AE #5

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 (21)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 JAN 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 (22)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication CODEINE-GUAIFEN

Prophylaxis Yes ☐
No ☒

Indication AE #5

Dose per administration 10-100

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 (22)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA EXACERBATION

Dose per administration 125

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 8 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication MILD INTERMITTENT ASTHMA
EXACERBATION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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)	10 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication SINGULAIR

Prophylaxis Yes ☐
No ☒

Indication ASTHMA EXACERBATION

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 (25)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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)	02 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication FLUTICASONE PROPIONATE
SALMETEROL DISKUS

Prophylaxis Yes ☐
No ☒

Indication ASTHMA EXACERBATION

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)		02 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ASTHMA EXACERBATION

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 (27)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication ASTHMA EXACERBATION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

Name of Medication ALBUTEROL CFC

Prophylaxis Yes ☐
No ☒

Indication ASTHMA EXACERBATION

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

504 of 3358

EAB) (1725)

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 20 Apr 2021 15:50:26

Generated On: 10 Jun 2021 08:08:32

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3532276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3532276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 03:59:57

Generated On: 10 Jun 2021 08:08:32

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 OCT 2020	BROKEN CROWN ON TOOTH REPAIRED	Adverse Event	

US3532276

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:08:32

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

US3532276

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:08:32

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 ☐

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

SAEID	USA-US077-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	1

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Apr 2021 04:00:25

Generated On: 10 Jun 2021 08:08:32

SAEID	USA-US077-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	1
Date of submission (Pre-filled from custom function)	11/FEB/2021 14:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3532276 (Prod: Children's Healthcare of Atlanta)

US3532276

Form: Participant Creation

Generated On: 10 Jun 2021 08:08:32

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'US3532276'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:34:20

US3532276

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:06:52

US3532276

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:34:21

US3532276

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	10 Sep 2020 15:06:52

US3532276

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'SCRN'	System	10 Sep 2020 15:06:52

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered (b) (6) 1942'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:34:22

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '77'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'YEARS'	System	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '78'	System	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Female (F)'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'I'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:08:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:07

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Sep 2020'	System	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2020'	System	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Amendment 3 (3)'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:07:35

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 14:34:21

US3532276

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:08:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'I'	System	10 Sep 2020 15:16:34

US3532276

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:16:34

US3532276

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:08:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:04

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:57:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:57:39
Data point term sent to Coder	System	10 Sep 2020 16:56:53
User entered 'Allergy to Sulfa'	(b) (4), (b) (6)	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2017'	System	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2017'	System	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:56:31

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:59:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:59:46
Data point term sent to Coder	System	10 Sep 2020 16:57:54
User entered 'Allergy to Antifungal Drugs'	(b) (4), (b) (6)	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2000'	System	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2000'	System	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:56:54

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergy to vaccine, LLT: Allergy to vaccine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 18:35:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:35:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergy to vaccine, LLT: Allergy to vaccine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:34:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:34:39
Data point term sent to Coder	System	10 Sep 2020 16:57:54
User entered 'Allergy to Tetanus shot'	(b) (4), (b) (6)	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1945'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1945'	System	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1945'	System	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:57:15

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:58:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:58:43
Data point term sent to Coder	System	10 Sep 2020 16:57:56
User entered 'Mild intermediate Asthma'	(b) (4), (b) (6)	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2009'	System	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2009'	System	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:57:55

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:59:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:59:47
Data point term sent to Coder	System	10 Sep 2020 16:59:03
User entered 'High Cholesterol'	(b) (4), (b) (6)	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2019'	System	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2019'	System	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:58:19

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
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)	10 Sep 2020 16:59:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:59:47
Data point term sent to Coder	System	10 Sep 2020 16:59:03
User entered 'Hypertension'	(b) (4), (b) (6)	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2018'	System	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2018'	System	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:58:44

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:59:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:59:47
Data point term sent to Coder	System	10 Sep 2020 16:59:05
User entered 'Osteoarthritis'	(b) (4), (b) (6)	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2005'	System	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2005'	System	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 16:59:01

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:21:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:21:39
Data point term sent to Coder	System	10 Sep 2020 17:21:08
User entered 'Hysterectomy'	(b) (4), (b) (6)	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1982'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1982'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1982'	System	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1982'	System	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1982'	System	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1982'	System	10 Sep 2020 17:20:09

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:21:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:21:39
Data point term sent to Coder	System	10 Sep 2020 17:21:08
User entered 'Menopause'	(b) (4), (b) (6)	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1981'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1981'	System	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1981'	System	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:20:30

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal skin infection, LLT: Fungal dermatitis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 06:26:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 06:26:34
Data point term sent to Coder	System	18 Sep 2020 12:22:59
Coding entries removed.	Lisa Macoy (b) (4)	18 Sep 2020 12:22:41
User entered 'CANDIDAL DERMATITIS' reason for change: Data Entry Error	Lisa Macoy (b) (4)	18 Sep 2020 12:22:41
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Fungal skin infection, LLT: Fungal dermatitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 04:54:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 04:54:47
Data point term sent to Coder	System	10 Sep 2020 17:21:09
User entered 'Candid Dermatitis'	(b) (4), (b) (6)	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jun 2020'	System	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2020'	System	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:20:57

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:22:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:22:43
Data point term sent to Coder	System	10 Sep 2020 17:22:09
User entered 'Hypothyroidism'	(b) (4), (b) (6)	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2000'	System	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2000'	System	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:21:18

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee total replacement - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:22:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:22:43
Data point term sent to Coder	System	10 Sep 2020 17:22:10
User entered 'Right Knee total replacement'	(b) (4), (b) (6)	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un Aug 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un Aug 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Aug 2010'	System	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2010'	System	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Aug 2010'	System	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2010'	System	10 Sep 2020 17:21:48

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee total replacement - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:23:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:23:48
Data point term sent to Coder	System	10 Sep 2020 17:23:11
User entered 'Left knee total replacement'	(b) (4), (b) (6)	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2007'	System	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2007'	System	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2007'	System	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2007'	System	10 Sep 2020 17:22:21

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:23:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:23:48
Data point term sent to Coder	System	10 Sep 2020 17:23:11
User entered 'GERD'	(b) (4), (b) (6)	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2014'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2014'	System	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2014'	System	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:22:34

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:23:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:23:47
Data point term sent to Coder	System	10 Sep 2020 17:23:12
User entered 'Tonsillectomy'	(b) (4), (b) (6)	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1944'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1944'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1944'	System	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1944'	System	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1944'	System	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1944'	System	10 Sep 2020 17:23:04

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tenoplasty, LLT: Tendon repair - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 21:06:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 21:06:05
Data point term sent to Coder	System	10 Sep 2020 17:24:13
User entered 'Left knee tendon repair'	(b) (4), (b) (6)	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1961'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1961'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1961'	System	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1961'	System	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1961'	System	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1961'	System	10 Sep 2020 17:23:32

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:24:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:24:39
Data point term sent to Coder	System	10 Sep 2020 17:24:13
User entered 'Right knee lateral release'	(b) (4), (b) (6)	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1989'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1989'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1989'	System	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1989'	System	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1989'	System	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1989'	System	10 Sep 2020 17:24:05

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Gallbladder removal - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 19:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 19:10:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:26:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:26:44
Data point term sent to Coder	System	10 Sep 2020 17:25:18
User entered 'Gall bladder removal'	(b) (4), (b) (6)	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1990'	System	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1990'	System	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1990'	System	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1990'	System	10 Sep 2020 17:24:43

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon injury, LLT: Achilles tendon injury - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 08:38:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 08:38:44
Data point term sent to Coder	System	10 Sep 2020 17:26:18
User entered 'Ruputred achilles tendon'	(b) (4), (b) (6)	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1992'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1992'	System	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1992'	System	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:25:18

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle operation, LLT: Ankle operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:27:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:27:49
Data point term sent to Coder	System	10 Sep 2020 17:26:18
User entered 'Right ankle surgery'	(b) (4), (b) (6)	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1993'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1993'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1993'	System	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1993'	System	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1993'	System	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1993'	System	10 Sep 2020 17:25:43

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
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.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:28:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:28:53
Data point term sent to Coder	System	10 Sep 2020 17:27:23
User entered 'Right rotator cuff repair'	(b) (4), (b) (6)	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2003'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2003'	System	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2003'	System	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2003'	System	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2003'	System	10 Sep 2020 17:26:54

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tendon operation, LLT: Tendon operation - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 00:19:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Sep 2020 00:19:39
Data point term sent to Coder	System	10 Sep 2020 17:28:25
User entered 'Left thumb tendon surgery'	(b) (4), (b) (6)	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2007'	System	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2007'	System	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2007'	System	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2007'	System	10 Sep 2020 17:27:31

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
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.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:28:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:28:53
Data point term sent to Coder	System	10 Sep 2020 17:28:25
User entered 'Left rotator cuff repair'	(b) (4), (b) (6)	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un Mar 2017'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un Mar 2017'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Mar 2017'	System	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2017'	System	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Mar 2017'	System	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2017'	System	10 Sep 2020 17:28:13

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:30:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:30:47
Data point term sent to Coder	System	10 Sep 2020 17:29:33
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1945'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 1945'	System	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '1945'	System	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	10 Sep 2020 17:28:33

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eye - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Nov 2020 06:20:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 06:20:32
Data point term sent to Coder	System	05 Nov 2020 19:06:59
User entered 'Dry left eye'	Lisa Macoy (b) (4)	05 Nov 2020 19:06:42
	(b) (4)	

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 2015'	Lisa Macoy (b) (4)	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'Jan 2015'	System	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '2015'	System	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	05 Nov 2020 19:06:42

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 15:08:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 15:08:50
Data point term sent to Coder	System	16 Apr 2021 15:07:48
User entered 'eczema'	Lisa Macoy (b) (4)	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered empty.	Lisa Macoy (b) (4)	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'I'	Lisa Macoy (b) (4)	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered empty.	Lisa Macoy (b) (4)	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '0'	Lisa Macoy (b) (4)	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered empty.	System	16 Apr 2021 15:06:48

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '10:20'	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '10 Sep 2020 10:20'	System	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '157.4' cm	(b) (4) Lisa Macoy (b) (4)	10 Sep 2020 15:53:55
DataPoint set to visible.	(b) (4) System	10 Sep 2020 15:16:34

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '82' kg	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55
DataPoint set to visible.	System	10 Sep 2020 15:16:34

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered '33.09820'	System	10 Sep 2020 15:53:55
DataPoint set to visible.	System	10 Sep 2020 15:16:34

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'kg/m2'	System	10 Sep 2020 15:53:55
DataPoint set to visible.	System	10 Sep 2020 15:16:34

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'bpm'	System	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'breaths/min'	System	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'mmHg'	System	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User entered 'mmHg'	System	10 Sep 2020 15:53:55

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20

US3532276

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20

US3532276

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:16:46

US3532276

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 15:16:46

US3532276

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:16

US3532276

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:32

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:16

US3532276

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:32

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:16

US3532276

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:17:16

US3532276

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:17:16

US3532276

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:32

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:16

US3532276

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:32

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'un UNK 1981'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:16

US3532276

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:08:32

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:16

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

[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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

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[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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'retired'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Folder: Screening

Form: Risk of Exposure

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[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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Folder: Screening

Form: Risk of Exposure

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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)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'I'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '0'	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:08:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:17:20
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:19:18

US3532276

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:29

US3532276

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:29

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	10 Sep 2020 15:17:29

US3532276

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'VISIT1'	System	10 Sep 2020 15:17:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '10 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:24:28

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:32

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '190536'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:24:28

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:32

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 15:24:28

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:32

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:55:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:32

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:55:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:32

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:55:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:32

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:55:37

US3532276

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:08:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:55:37

US3532276

Folder: Visit 1 Day 1

Form: Randomization

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[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Etza Peters (b) (4)	25 Sep 2020 16:31:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:57:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:57:35

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Macoy (b) (4) (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 16:24:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 16:24:01
User entered '10:20' reason for change: Data Entry Error	Lisa Macoy (b) (4)	10 Sep 2020 16:24:01
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 16:21:10
User entered empty.	System	10 Sep 2020 16:21:10
	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered '10 Sep 2020 10:20'	System	10 Sep 2020 16:24:01
User entered empty.	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '97.9' F	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '73'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'bpm'	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '20'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'breaths/min'	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '146'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'mmHg'	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '90'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'mmHg'	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '12:14'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered '10 Sep 2020 12:14'	System	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '97.7' F	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '71'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'bpm'	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '20'	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'breaths/min'	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 16:25:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 16:25:13
User entered '144' reason for change: Data Entry Error	Lisa Macoy (b) (4)	10 Sep 2020 16:25:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 16:21:10
User entered empty.	System	10 Sep 2020 16:21:10
	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10
	(b) (4)	

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'mmHg'	System	10 Sep 2020 16:25:13
User entered empty.	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 16:25:13
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 16:25:13
User entered '86' reason for change: Data Entry Error	Lisa Macoy (b) (4)	10 Sep 2020 16:25:13
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 16:21:10
User entered empty.	System	10 Sep 2020 16:21:10
	Lisa Macoy (b) (4)	10 Sep 2020 16:21:10
	(b) (4)	

US3532276

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'mmHg'	System	10 Sep 2020 16:25:13
User entered empty.	System	10 Sep 2020 16:21:10

US3532276

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:08

US3532276

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:08

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '11:41'	Lisa Macoy (b) (4)	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered '10 Sep 2020 11:41'	System	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Left Arm (LEFT ARM)'	Lisa Macoy (b) (4)	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'ONCE'	System	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 16:14:52

US3532276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:24

US3532276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:24

US3532276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '11:26'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:24

US3532276

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered '10 Sep 2020 11:26'	System	10 Sep 2020 15:54:24

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '10 Sep 2020'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lisa Macoy (b) (4) (b) (4)	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '11:18'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered '10 Sep 2020 11:18'	System	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lisa Macoy (b) (4) (b) (4)	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:32

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered empty.	System	10 Sep 2020 15:54:55

US3532276

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Sep 2020 16:17:41

US3532276

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered '1'	System	10 Sep 2020 16:17:41

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:18:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'e399dd3a-0e40-4887-8b19-016474216b4e' User entered 'Yes (Y)'	System	10 Sep 2020 16:19:07
	System	10 Sep 2020 16:19:07

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:18:36', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'e399dd3a-0e40-4887-8b19-016474216b4e' User entered '97.7'	System	10 Sep 2020 16:19:07
	System	10 Sep 2020 16:19:07

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:18:44', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'e399dd3a-0e40-4887-8b19-016474216b4e' User entered 'No (N)'	System	10 Sep 2020 16:19:07
	System	10 Sep 2020 16:19:07

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:19:02', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'e399dd3a-0e40-4887-8b19-016474216b4e' User entered '10 Sep 2020 12:19'	System	10 Sep 2020 16:19:07
	System	10 Sep 2020 16:19:07

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 12:01'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 14:31'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:43:15', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8a80a0e1-01e0-4911-bb7a-806d462f1903' User entered 'Yes (Y)'	System	11 Sep 2020 02:44:05
	System	11 Sep 2020 02:44:05

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:43:26', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8a80a0e1-01e0-4911-bb7a-806d462f1903' User entered '96.8'	System	11 Sep 2020 02:44:05
	System	11 Sep 2020 02:44:05

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:43:31', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8a80a0e1-01e0-4911-bb7a-806d462f1903'	System	11 Sep 2020 02:44:05
User entered 'No (N)'	System	11 Sep 2020 02:44:05

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8a80a0e1-01e0-4911-bb7a-806d462f1903' User entered '10 Sep 2020 22:44'	System	11 Sep 2020 02:44:05
	System	11 Sep 2020 02:44:05

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 15:26'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 2'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:12:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '40cb4b12-aa76-4ee4-85df-cddc92f4df96'	System	12 Sep 2020 10:12:37
User entered 'Yes (Y)'	System	12 Sep 2020 10:12:37

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:12:24', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '40cb4b12-aa76-4ee4-85df-cddc92f4df96'	System	12 Sep 2020 10:12:37
User entered '97.8'	System	12 Sep 2020 10:12:37

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:12:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '40cb4b12-aa76-4ee4-85df-cddc92f4df96'	System	12 Sep 2020 10:12:37
User entered 'No (N)'	System	12 Sep 2020 10:12:37

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:12:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '40cb4b12-aa76-4ee4-85df-cddc92f4df96'	System	12 Sep 2020 10:12:37
User entered '12 Sep 2020 06:12'	System	12 Sep 2020 10:12:37

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 3'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:22:39', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a63611b4-b273-4039-9b4c-9eeef0b8bda0' User entered 'Yes (Y)'	System	12 Sep 2020 17:22:59
	System	12 Sep 2020 17:22:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:22:47', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a63611b4-b273-4039-9b4c-9eeef0b8bda0' User entered '96.5'	System	12 Sep 2020 17:22:59
	System	12 Sep 2020 17:22:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:22:51', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a63611b4-b273-4039-9b4c-9eeef0b8bda0'	System	12 Sep 2020 17:22:59
User entered 'No (N)'	System	12 Sep 2020 17:22:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:22:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a63611b4-b273-4039-9b4c-9eeef0b8bda0' User entered '12 Sep 2020 13:22'	System	12 Sep 2020 17:22:59
	System	12 Sep 2020 17:22:59

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 4'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:27:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7aaca36e-d362-4018-80d0-a3401742b862' User entered 'Yes (Y)'	System	13 Sep 2020 23:27:37
	System	13 Sep 2020 23:27:37

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:27:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7aaca36e-d362-4018-80d0-a3401742b862' User entered '97.7'	System	13 Sep 2020 23:27:37
	System	13 Sep 2020 23:27:37

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:27:27', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7aaca36e-d362-4018-80d0-a3401742b862'	System	13 Sep 2020 23:27:37
User entered 'No (N)'	System	13 Sep 2020 23:27:37

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:27:34', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7aaca36e-d362-4018-80d0-a3401742b862'	System	13 Sep 2020 23:27:37
User entered '13 Sep 2020 19:27'	System	13 Sep 2020 23:27:37

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 5'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:57:48', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6ae70089-6e00-4036-9b7d-7869223f193f' User entered 'Yes (Y)'	System	14 Sep 2020 20:58:17
	System	14 Sep 2020 20:58:17

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:57:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6ae70089-6e00-4036-9b7d-7869223f193f' User entered '97.7'	System	14 Sep 2020 20:58:17
	System	14 Sep 2020 20:58:17

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:58:08', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6ae70089-6e00-4036-9b7d-7869223f193f' User entered 'No (N)'	System	14 Sep 2020 20:58:17
	System	14 Sep 2020 20:58:17

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:58:14', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6ae70089-6e00-4036-9b7d-7869223f193f' User entered '14 Sep 2020 16:58'	System	14 Sep 2020 20:58:17
	System	14 Sep 2020 20:58:17

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 6'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:07:59', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '18fe26cb-f7b6-4c4f-9784-f6c3cd64de98' User entered 'Yes (Y)'	System	15 Sep 2020 21:08:28
	System	15 Sep 2020 21:08:28

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:05', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '18fe26cb-f7b6-4c4f-9784-f6c3cd64de98' User entered '97.6'	System	15 Sep 2020 21:08:28
	System	15 Sep 2020 21:08:28

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '18fe26cb-f7b6-4c4f-9784-f6c3cd64de98' User entered 'No (N)'	System	15 Sep 2020 21:08:28
	System	15 Sep 2020 21:08:28

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '18fe26cb-f7b6-4c4f-9784-f6c3cd64de98' User entered '15 Sep 2020 17:08'	System	15 Sep 2020 21:08:28
	System	15 Sep 2020 21:08:28

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 7'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:28:39', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bd513d0d-c1bb-4445-a764-a50d209da29d' User entered 'Yes (Y)'	System	16 Sep 2020 20:29:09
	System	16 Sep 2020 20:29:09

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:28:46', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bd513d0d-c1bb-4445-a764-a50d209da29d' User entered '97.3'	System	16 Sep 2020 20:29:09
	System	16 Sep 2020 20:29:09

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:28:52', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bd513d0d-c1bb-4445-a764-a50d209da29d'	System	16 Sep 2020 20:29:09
User entered 'No (N)'	System	16 Sep 2020 20:29:09

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:04', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bd513d0d-c1bb-4445-a764-a50d209da29d' User entered '16 Sep 2020 16:29'	System	16 Sep 2020 20:29:09
	System	16 Sep 2020 20:29:09

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:19:51', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9bcaa61a-709d-4a9a-b5fa-0f718bflc183' User entered 'None (1)'	System	10 Sep 2020 16:20:40
	System	10 Sep 2020 16:20:40

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:20:02', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9bcaa61a-709d-4a9a-b5fa-0f718bf1c183'	System	10 Sep 2020 16:20:40
User entered 'No (N)'	System	10 Sep 2020 16:20:40

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:20:27', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9bcaa61a-709d-4a9a-b5fa-0f718bf1c183' User entered 'No (N)'	System	10 Sep 2020 16:20:40
	System	10 Sep 2020 16:20:40

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:20:15', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9bcaa61a-709d-4a9a-b5fa-0f718bflc183' User entered 'None (1)'	System	10 Sep 2020 16:20:40
	System	10 Sep 2020 16:20:40

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:20:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9bcaa61a-709d-4a9a-b5fa-0f718bf1c183' User entered '10 Sep 2020 12:20'	System	10 Sep 2020 16:20:40
	System	10 Sep 2020 16:20:40

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 12:01'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 14:31'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:12', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c274d0ed-1213-4781-a489-13f3505b17c1' User entered 'None (1)'	System	11 Sep 2020 02:44:38
	System	11 Sep 2020 02:44:38

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c274d0ed-1213-4781-a489-13f3505b17c1' User entered 'No (N)'	System	11 Sep 2020 02:44:38
	System	11 Sep 2020 02:44:38

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:22', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c274d0ed-1213-4781-a489-13f3505b17c1' User entered 'No (N)'	System	11 Sep 2020 02:44:38
	System	11 Sep 2020 02:44:38

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:27', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c274d0ed-1213-4781-a489-13f3505b17c1' User entered 'None (1)'	System	11 Sep 2020 02:44:38
	System	11 Sep 2020 02:44:38

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c274d0ed-1213-4781-a489-13f3505b17c1' User entered '10 Sep 2020 22:44'	System	11 Sep 2020 02:44:38
	System	11 Sep 2020 02:44:38

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 15:26'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 2'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:12:42', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '00b5f5dc-c868-4a72-8139-81dd5699b190' User entered 'None (1)'	System	12 Sep 2020 10:13:06
	System	12 Sep 2020 10:13:06

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:12:48', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '00b5f5dc-c868-4a72-8139-81dd5699b190' User entered 'No (N)'	System	12 Sep 2020 10:13:06
	System	12 Sep 2020 10:13:06

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:12:52', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '00b5f5dc-c868-4a72-8139-81dd5699b190' User entered 'No (N)'	System	12 Sep 2020 10:13:06
	System	12 Sep 2020 10:13:06

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:12:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '00b5f5dc-c868-4a72-8139-81dd5699b190' User entered 'None (1)'	System	12 Sep 2020 10:13:06
	System	12 Sep 2020 10:13:06

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '00b5f5dc-c868-4a72-8139-81dd5699b190' User entered '12 Sep 2020 06:13'	System	12 Sep 2020 10:13:06
	System	12 Sep 2020 10:13:06

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 3'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '37fd05f0-4bae-4f48-9ad3-4518a9296c50'	System	12 Sep 2020 17:23:23
User entered 'None (1)'	System	12 Sep 2020 17:23:23

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:06', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '37fd05f0-4bae-4f48-9ad3-4518a9296c50'	System	12 Sep 2020 17:23:23
User entered 'No (N)'	System	12 Sep 2020 17:23:23

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:10', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '37fd05f0-4bae-4f48-9ad3-4518a9296c50' User entered 'No (N)'	System	12 Sep 2020 17:23:23
	System	12 Sep 2020 17:23:23

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:14', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '37fd05f0-4bae-4f48-9ad3-4518a9296c50'	System	12 Sep 2020 17:23:23
User entered 'None (1)'	System	12 Sep 2020 17:23:23

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:20', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '37fd05f0-4bae-4f48-9ad3-4518a9296c50' User entered '12 Sep 2020 13:23'	System	12 Sep 2020 17:23:23
	System	12 Sep 2020 17:23:23

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 4'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:27:41', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bb69ad9b-3ec2-4383-995a-f632cf9a454f' User entered 'None (1)'	System	13 Sep 2020 23:28:05
	System	13 Sep 2020 23:28:05

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:27:45', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bb69ad9b-3ec2-4383-995a-f632cf9a454f' User entered 'No (N)'	System	13 Sep 2020 23:28:05
	System	13 Sep 2020 23:28:05

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:27:51', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bb69ad9b-3ec2-4383-995a-f632cf9a454f' User entered 'No (N)'	System	13 Sep 2020 23:28:05
	System	13 Sep 2020 23:28:05

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:27:57', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bb69ad9b-3ec2-4383-995a-f632cf9a454f' User entered 'None (1)'	System	13 Sep 2020 23:28:05
	System	13 Sep 2020 23:28:05

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'bb69ad9b-3ec2-4383-995a-f632cf9a454f' User entered '13 Sep 2020 19:28'	System	13 Sep 2020 23:28:05
	System	13 Sep 2020 23:28:05

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 5'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:58:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51bbb3fb-b996-4111-bc9f-7f1b9718d7a3' User entered 'None (1)'	System	14 Sep 2020 20:58:48
	System	14 Sep 2020 20:58:48

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:58:27', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51bbb3fb-b996-4111-bc9f-7f1b9718d7a3' User entered 'No (N)'	System	14 Sep 2020 20:58:48
	System	14 Sep 2020 20:58:48

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:58:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51bbb3fb-b996-4111-bc9f-7f1b9718d7a3' User entered 'No (N)'	System	14 Sep 2020 20:58:48
	System	14 Sep 2020 20:58:48

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:58:40', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51bbb3fb-b996-4111-bc9f-7f1b9718d7a3' User entered 'None (1)'	System	14 Sep 2020 20:58:48
	System	14 Sep 2020 20:58:48

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:58:46', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51bbb3fb-b996-4111-bc9f-7f1b9718d7a3'	System	14 Sep 2020 20:58:48
User entered '14 Sep 2020 16:58'	System	14 Sep 2020 20:58:48

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 6'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:29', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8f48f2dc-6c5c-48af-ae23-6eba52c17250'	System	15 Sep 2020 21:08:50
User entered 'None (1)'	System	15 Sep 2020 21:08:50

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:32', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8f48f2dc-6c5c-48af-ae23-6eba52c17250' User entered 'No (N)'	System	15 Sep 2020 21:08:50
	System	15 Sep 2020 21:08:50

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:37', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8f48f2dc-6c5c-48af-ae23-6eba52c17250'	System	15 Sep 2020 21:08:50
User entered 'No (N)'	System	15 Sep 2020 21:08:50

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:41', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8f48f2dc-6c5c-48af-ae23-6eba52c17250'	System	15 Sep 2020 21:08:50
User entered 'None (1)'	System	15 Sep 2020 21:08:50

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:46', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '8f48f2dc-6c5c-48af-ae23-6eba52c17250' User entered '15 Sep 2020 17:08'	System	15 Sep 2020 21:08:50
	System	15 Sep 2020 21:08:50

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 7'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:14', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a7083a0b-7499-4b41-8b53-63acd5252b60'	System	16 Sep 2020 20:29:32
User entered 'None (1)'	System	16 Sep 2020 20:29:32

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a7083a0b-7499-4b41-8b53-63acd5252b60'	System	16 Sep 2020 20:29:32
User entered 'No (N)'	System	16 Sep 2020 20:29:32

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:22', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a7083a0b-7499-4b41-8b53-63acd5252b60'	System	16 Sep 2020 20:29:32
User entered 'No (N)'	System	16 Sep 2020 20:29:32

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:25', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a7083a0b-7499-4b41-8b53-63acd5252b60'	System	16 Sep 2020 20:29:32
User entered 'None (1)'	System	16 Sep 2020 20:29:32

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a7083a0b-7499-4b41-8b53-63acd5252b60'	System	16 Sep 2020 20:29:32
User entered '16 Sep 2020 16:29'	System	16 Sep 2020 20:29:32

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:20:49', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ec8f4a55-67a8-4e0a-b0b9-5df892ede1e5' User entered 'None (0)'	System	10 Sep 2020 16:21:36
	System	10 Sep 2020 16:21:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:20:55', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ec8f4a55-67a8-4e0a-b0b9-5df892ede1e5' User entered 'None (0)'	System	10 Sep 2020 16:21:36
	System	10 Sep 2020 16:21:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:21:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ec8f4a55-67a8-4e0a-b0b9-5df892ede1e5' User entered 'None (0)'	System	10 Sep 2020 16:21:36
	System	10 Sep 2020 16:21:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:21:05', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ec8f4a55-67a8-4e0a-b0b9-5df892ede1e5' User entered 'None (0)'	System	10 Sep 2020 16:21:36
	System	10 Sep 2020 16:21:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:21:09', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ec8f4a55-67a8-4e0a-b0b9-5df892ede1e5' User entered 'None (0)'	System	10 Sep 2020 16:21:36
	System	10 Sep 2020 16:21:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:21:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ec8f4a55-67a8-4e0a-b0b9-5df892ede1e5' User entered 'None (0)'	System	10 Sep 2020 16:21:36
	System	10 Sep 2020 16:21:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:21:20', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ec8f4a55-67a8-4e0a-b0b9-5df892ede1e5'	System	10 Sep 2020 16:21:36
User entered 'No (N)'	System	10 Sep 2020 16:21:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T12:21:29', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ec8f4a55-67a8-4e0a-b0b9-5df892ede1e5'	System	10 Sep 2020 16:21:36
User entered '10 Sep 2020 12:21'	System	10 Sep 2020 16:21:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 12:01'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 14:31'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:45', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6b8178e4-a5e4-471e-957b-f7c91e68fd50' User entered 'None (0)'	System	11 Sep 2020 02:45:27
	System	11 Sep 2020 02:45:27

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:52', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6b8178e4-a5e4-471e-957b-f7c91e68fd50' User entered 'None (0)'	System	11 Sep 2020 02:45:27
	System	11 Sep 2020 02:45:27

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:44:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6b8178e4-a5e4-471e-957b-f7c91e68fd50' User entered 'None (0)'	System	11 Sep 2020 02:45:27
	System	11 Sep 2020 02:45:27

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:45:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6b8178e4-a5e4-471e-957b-f7c91e68fd50' User entered 'None (0)'	System	11 Sep 2020 02:45:27
	System	11 Sep 2020 02:45:27

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:45:04', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6b8178e4-a5e4-471e-957b-f7c91e68fd50' User entered 'None (0)'	System	11 Sep 2020 02:45:27
	System	11 Sep 2020 02:45:27

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:45:08', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6b8178e4-a5e4-471e-957b-f7c91e68fd50' User entered 'None (0)'	System	11 Sep 2020 02:45:27
	System	11 Sep 2020 02:45:27

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:45:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6b8178e4-a5e4-471e-957b-f7c91e68fd50' User entered 'No (N)'	System	11 Sep 2020 02:45:27
	System	11 Sep 2020 02:45:27

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-10T22:45:24', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6b8178e4-a5e4-471e-957b-f7c91e68fd50' User entered '10 Sep 2020 22:45'	System	11 Sep 2020 02:45:27
	System	11 Sep 2020 02:45:27

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Sep 2020 15:26'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 2'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd2ab020-c82f-4992-8c78-82b8d8a8ba59' User entered 'None (0)'	System	12 Sep 2020 10:13:43
	System	12 Sep 2020 10:13:43

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:18', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd2ab020-c82f-4992-8c78-82b8d8a8ba59' User entered 'None (0)'	System	12 Sep 2020 10:13:43
	System	12 Sep 2020 10:13:43

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:22', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd2ab020-c82f-4992-8c78-82b8d8a8ba59' User entered 'None (0)'	System	12 Sep 2020 10:13:43
	System	12 Sep 2020 10:13:43

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:25', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd2ab020-c82f-4992-8c78-82b8d8a8ba59' User entered 'None (0)'	System	12 Sep 2020 10:13:43
	System	12 Sep 2020 10:13:43

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd2ab020-c82f-4992-8c78-82b8d8a8ba59' User entered 'None (0)'	System	12 Sep 2020 10:13:43
	System	12 Sep 2020 10:13:43

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:32', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd2ab020-c82f-4992-8c78-82b8d8a8ba59' User entered 'None (0)'	System	12 Sep 2020 10:13:43
	System	12 Sep 2020 10:13:43

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd2ab020-c82f-4992-8c78-82b8d8a8ba59' User entered 'No (N)'	System	12 Sep 2020 10:13:43
	System	12 Sep 2020 10:13:43

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T06:13:40', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd2ab020-c82f-4992-8c78-82b8d8a8ba59'	System	12 Sep 2020 10:13:43
User entered '12 Sep 2020 06:13'	System	12 Sep 2020 10:13:43

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 3'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:26', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dea9037e-d717-435c-9298-ee4c7d6dfec7' User entered 'None (0)'	System	12 Sep 2020 17:24:05
	System	12 Sep 2020 17:24:05

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dea9037e-d717-435c-9298-ee4c7d6dfec7' User entered 'None (0)'	System	12 Sep 2020 17:24:05
	System	12 Sep 2020 17:24:05

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:38', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dea9037e-d717-435c-9298-ee4c7d6dfec7' User entered 'None (0)'	System	12 Sep 2020 17:24:05
	System	12 Sep 2020 17:24:05

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:42', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dea9037e-d717-435c-9298-ee4c7d6dfec7' User entered 'None (0)'	System	12 Sep 2020 17:24:05
	System	12 Sep 2020 17:24:05

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:46', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dea9037e-d717-435c-9298-ee4c7d6dfec7' User entered 'None (0)'	System	12 Sep 2020 17:24:05
	System	12 Sep 2020 17:24:05

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:49', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dea9037e-d717-435c-9298-ee4c7d6dfec7' User entered 'None (0)'	System	12 Sep 2020 17:24:05
	System	12 Sep 2020 17:24:05

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:23:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dea9037e-d717-435c-9298-ee4c7d6dfec7' User entered 'No (N)'	System	12 Sep 2020 17:24:05
	System	12 Sep 2020 17:24:05

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-12T13:24:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dea9037e-d717-435c-9298-ee4c7d6dfec7' User entered '12 Sep 2020 13:24'	System	12 Sep 2020 17:24:05
	System	12 Sep 2020 17:24:05

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 4'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:12', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '109eda98-13a6-4dcb-aa05-b6e13b7d6439' User entered 'None (0)'	System	13 Sep 2020 23:28:53
	System	13 Sep 2020 23:28:53

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:19', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '109eda98-13a6-4dcb-aa05-b6e13b7d6439' User entered 'None (0)'	System	13 Sep 2020 23:28:53
	System	13 Sep 2020 23:28:53

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:26', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '109eda98-13a6-4dcb-aa05-b6e13b7d6439' User entered 'None (0)'	System	13 Sep 2020 23:28:53
	System	13 Sep 2020 23:28:53

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:32', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '109eda98-13a6-4dcb-aa05-b6e13b7d6439' User entered 'None (0)'	System	13 Sep 2020 23:28:53
	System	13 Sep 2020 23:28:53

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:37', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '109eda98-13a6-4dcb-aa05-b6e13b7d6439' User entered 'None (0)'	System	13 Sep 2020 23:28:53
	System	13 Sep 2020 23:28:53

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:41', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '109eda98-13a6-4dcb-aa05-b6e13b7d6439' User entered 'None (0)'	System	13 Sep 2020 23:28:53
	System	13 Sep 2020 23:28:53

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:46', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '109eda98-13a6-4dcb-aa05-b6e13b7d6439' User entered 'No (N)'	System	13 Sep 2020 23:28:53
	System	13 Sep 2020 23:28:53

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-13T19:28:50', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '109eda98-13a6-4dcb-aa05-b6e13b7d6439' User entered '13 Sep 2020 19:28'	System	13 Sep 2020 23:28:53
	System	13 Sep 2020 23:28:53

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 5'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:59:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '107775dc-93c7-436d-b6c7-6375df12d61e' User entered 'None (0)'	System	14 Sep 2020 21:00:00
	System	14 Sep 2020 21:00:00

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:59:07', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '107775dc-93c7-436d-b6c7-6375df12d61e' User entered 'None (0)'	System	14 Sep 2020 21:00:00
	System	14 Sep 2020 21:00:00

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:59:18', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '107775dc-93c7-436d-b6c7-6375df12d61e' User entered 'None (0)'	System	14 Sep 2020 21:00:00
	System	14 Sep 2020 21:00:00

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:59:24', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '107775dc-93c7-436d-b6c7-6375df12d61e' User entered 'None (0)'	System	14 Sep 2020 21:00:00
	System	14 Sep 2020 21:00:00

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:59:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '107775dc-93c7-436d-b6c7-6375df12d61e' User entered 'None (0)'	System	14 Sep 2020 21:00:00
	System	14 Sep 2020 21:00:00

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:59:32', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '107775dc-93c7-436d-b6c7-6375df12d61e' User entered 'None (0)'	System	14 Sep 2020 21:00:00
	System	14 Sep 2020 21:00:00

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:59:39', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '107775dc-93c7-436d-b6c7-6375df12d61e' User entered 'No (N)'	System	14 Sep 2020 21:00:00
	System	14 Sep 2020 21:00:00

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-14T16:59:57', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '107775dc-93c7-436d-b6c7-6375df12d61e' User entered '14 Sep 2020 16:59'	System	14 Sep 2020 21:00:00
	System	14 Sep 2020 21:00:00

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 6'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:52', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '561049a6-5a4a-4271-a3e9-7302fa53171e' User entered 'None (0)'	System	15 Sep 2020 21:09:36
	System	15 Sep 2020 21:09:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:08:57', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '561049a6-5a4a-4271-a3e9-7302fa53171e' User entered 'None (0)'	System	15 Sep 2020 21:09:36
	System	15 Sep 2020 21:09:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:09:01', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '561049a6-5a4a-4271-a3e9-7302fa53171e' User entered 'None (0)'	System	15 Sep 2020 21:09:36
	System	15 Sep 2020 21:09:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:09:06', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '561049a6-5a4a-4271-a3e9-7302fa53171e' User entered 'None (0)'	System	15 Sep 2020 21:09:36
	System	15 Sep 2020 21:09:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:09:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '561049a6-5a4a-4271-a3e9-7302fa53171e' User entered 'None (0)'	System	15 Sep 2020 21:09:36
	System	15 Sep 2020 21:09:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:09:24', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '561049a6-5a4a-4271-a3e9-7302fa53171e' User entered 'None (0)'	System	15 Sep 2020 21:09:36
	System	15 Sep 2020 21:09:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:09:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '561049a6-5a4a-4271-a3e9-7302fa53171e' User entered 'No (N)'	System	15 Sep 2020 21:09:36
	System	15 Sep 2020 21:09:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-15T17:09:32', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '561049a6-5a4a-4271-a3e9-7302fa53171e' User entered '15 Sep 2020 17:09'	System	15 Sep 2020 21:09:36
	System	15 Sep 2020 21:09:36

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 7'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3339a4d3-4d1e-4c5e-881b-1b4c61705c7c' User entered 'None (0)'	System	16 Sep 2020 20:30:10
	System	16 Sep 2020 20:30:10

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:40', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3339a4d3-4d1e-4c5e-881b-1b4c61705c7c' User entered 'None (0)'	System	16 Sep 2020 20:30:10
	System	16 Sep 2020 20:30:10

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:44', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3339a4d3-4d1e-4c5e-881b-1b4c61705c7c' User entered 'None (0)'	System	16 Sep 2020 20:30:10
	System	16 Sep 2020 20:30:10

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:47', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3339a4d3-4d1e-4c5e-881b-1b4c61705c7c' User entered 'None (0)'	System	16 Sep 2020 20:30:10
	System	16 Sep 2020 20:30:10

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:50', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3339a4d3-4d1e-4c5e-881b-1b4c61705c7c' User entered 'None (0)'	System	16 Sep 2020 20:30:10
	System	16 Sep 2020 20:30:10

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:29:53', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3339a4d3-4d1e-4c5e-881b-1b4c61705c7c' User entered 'None (0)'	System	16 Sep 2020 20:30:10
	System	16 Sep 2020 20:30:10

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:30:01', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3339a4d3-4d1e-4c5e-881b-1b4c61705c7c' User entered 'No (N)'	System	16 Sep 2020 20:30:10
	System	16 Sep 2020 20:30:10

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-09-16T16:30:08', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3339a4d3-4d1e-4c5e-881b-1b4c61705c7c' User entered '16 Sep 2020 16:30'	System	16 Sep 2020 20:30:10
	System	16 Sep 2020 20:30:10

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 16:14:52

US3532276

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	18 Sep 2020 12:13:28

US3532276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '18 Sep 2020'	Lisa Macoy (b) (4)	18 Sep 2020 12:13:28

US3532276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	18 Sep 2020 12:13:28

US3532276

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	18 Sep 2020 12:13:28

US3532276

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	18 Sep 2020 12:13:33

US3532276

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'I'	System	18 Sep 2020 12:13:33

US3532276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	25 Sep 2020 19:49:51

US3532276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '25 Sep 2020'	Lisa Macoy (b) (4)	25 Sep 2020 19:49:51

US3532276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	25 Sep 2020 19:49:51

US3532276

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	25 Sep 2020 19:49:51

US3532276

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	25 Sep 2020 19:49:55

US3532276

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'I'	System	25 Sep 2020 19:49:55

US3532276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	01 Oct 2020 18:51:57

US3532276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '1 Oct 2020'	Lisa Macoy (b) (4)	01 Oct 2020 18:51:57

US3532276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	01 Oct 2020 18:51:57

US3532276

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	01 Oct 2020 18:51:57

US3532276

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	01 Oct 2020 18:52:02

US3532276

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'I'	System	01 Oct 2020 18:52:02

US3532276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	08 Oct 2020 13:53:29

US3532276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '8 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 13:53:29

US3532276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	08 Oct 2020 13:53:29

US3532276

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'VISIT2'	System	08 Oct 2020 13:53:29

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Macoy (b) (4) (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '8 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '09:20'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered '8 Oct 2020 09:20'	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '97' F	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '77'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'bpm'	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '18'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'breaths/min'	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '116'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'mmHg'	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '77'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'mmHg'	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '8 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:31:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Oct 2020 14:31:09
User entered '10:29' reason for change: Data Entry Error	Lisa Macoy (b) (4)	08 Oct 2020 14:31:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:22:56
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered '8 Oct 2020 10:29'	System	08 Oct 2020 14:31:09
User entered empty.	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:31:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Oct 2020 14:31:09
User entered '97.7' F reason for change: Data Entry Error	Lisa Macoy (b) (4)	08 Oct 2020 14:31:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:22:56
User entered empty.	System	08 Oct 2020 14:22:56
	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:31:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Oct 2020 14:31:14
User entered 'Oral (Oral)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	08 Oct 2020 14:31:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:31:09
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:31:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Oct 2020 14:31:09
User entered '74' reason for change: Data Entry Error	Lisa Macoy (b) (4)	08 Oct 2020 14:31:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:22:56
User entered empty.	System	08 Oct 2020 14:22:56
	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'bpm'	System	08 Oct 2020 14:31:09
User entered empty.	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:31:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Oct 2020 14:31:09
User entered '18' reason for change: Data Entry Error	Lisa Macoy (b) (4)	08 Oct 2020 14:31:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:22:56
User entered empty.	System	08 Oct 2020 14:22:56
	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'breaths/min'	System	08 Oct 2020 14:31:09
User entered empty.	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:31:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Oct 2020 14:31:09
User entered '106' reason for change: Data Entry Error	Lisa Macoy (b) (4)	08 Oct 2020 14:31:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:22:56
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'mmHg'	System	08 Oct 2020 14:31:09
User entered empty.	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:31:09
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	08 Oct 2020 14:31:09
User entered '64' reason for change: Data Entry Error	Lisa Macoy (b) (4)	08 Oct 2020 14:31:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 14:22:56
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:22:56
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'mmHg'	System	08 Oct 2020 14:31:09
User entered empty.	System	08 Oct 2020 14:22:56

US3532276

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	08 Oct 2020 14:02:48

US3532276

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '8 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 14:02:48

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '8 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '09:56'	Lisa Macoy (b) (4)	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered '8 Oct 2020 09:56'	System	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Left Arm (LEFT ARM)'	Lisa Macoy (b) (4)	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'ONCE'	System	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 14:05:15

US3532276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	08 Oct 2020 14:06:16

US3532276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '8 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 14:06:16

US3532276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '09:35'	Lisa Macoy (b) (4)	08 Oct 2020 14:06:16

US3532276

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered '8 Oct 2020 09:35'	System	08 Oct 2020 14:06:16

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '8 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lisa Macoy (b) (4) (b) (4)	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '09:46'	Lisa Macoy (b) (4)	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:08:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered '8 Oct 2020 09:46'	System	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lisa Macoy (b) (4) (b) (4)	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Lisa Macoy (b) (4)	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:08:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered empty.	System	08 Oct 2020 14:06:33

US3532276

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	08 Oct 2020 14:31:20

US3532276

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'I'	System	08 Oct 2020 14:31:20

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:30:58', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4df1025a-72aa-48c5-a53c-2489b74659df' User entered 'Yes (Y)'	System	08 Oct 2020 14:31:19
	System	08 Oct 2020 14:31:19

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:04', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4df1025a-72aa-48c5-a53c-2489b74659df' User entered '97.7'	System	08 Oct 2020 14:31:19
	System	08 Oct 2020 14:31:19

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:09', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4df1025a-72aa-48c5-a53c-2489b74659df' User entered 'No (N)'	System	08 Oct 2020 14:31:19
	System	08 Oct 2020 14:31:19

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4df1025a-72aa-48c5-a53c-2489b74659df' User entered '08 Oct 2020 10:31'	System	08 Oct 2020 14:31:19
	System	08 Oct 2020 14:31:19

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 10:16'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 12:46'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:32:58', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a88b9232-ed80-41c6-8853-fdac8be9f5f2'	System	08 Oct 2020 21:33:28
User entered 'Yes (Y)'	System	08 Oct 2020 21:33:28

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:33:12', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a88b9232-ed80-41c6-8853-fdac8be9f5f2'	System	08 Oct 2020 21:33:28
User entered '97.5'	System	08 Oct 2020 21:33:28

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:33:18', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a88b9232-ed80-41c6-8853-fdac8be9f5f2'	System	08 Oct 2020 21:33:28
User entered 'No (N)'	System	08 Oct 2020 21:33:28

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:33:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a88b9232-ed80-41c6-8853-fdac8be9f5f2'	System	08 Oct 2020 21:33:28
User entered '08 Oct 2020 17:33'	System	08 Oct 2020 21:33:28

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 13:41'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 2'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:10:34', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '1eee29d7-9141-45f4-91e1-20bc9c23bfb0' User entered 'Yes (Y)'	System	09 Oct 2020 20:11:03
	System	09 Oct 2020 20:11:03

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:10:53', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '1eee29d7-9141-45f4-91e1-20bc9c23bfb0' User entered '98.2'	System	09 Oct 2020 20:11:03
	System	09 Oct 2020 20:11:03

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:10:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '1eee29d7-9141-45f4-91e1-20bc9c23bfb0' User entered 'No (N)'	System	09 Oct 2020 20:11:03
	System	09 Oct 2020 20:11:03

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '1eee29d7-9141-45f4-91e1-20bc9c23bfb0' User entered '09 Oct 2020 16:11'	System	09 Oct 2020 20:11:03
	System	09 Oct 2020 20:11:03

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 3'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:46:27', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51751f93-e78c-4972-9b54-00499093d7c4' User entered 'Yes (Y)'	System	10 Oct 2020 22:46:50
	System	10 Oct 2020 22:46:50

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:46:37', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51751f93-e78c-4972-9b54-00499093d7c4' User entered '97.2'	System	10 Oct 2020 22:46:50
	System	10 Oct 2020 22:46:50

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:46:40', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51751f93-e78c-4972-9b54-00499093d7c4' User entered 'No (N)'	System	10 Oct 2020 22:46:50
	System	10 Oct 2020 22:46:50

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:46:49', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '51751f93-e78c-4972-9b54-00499093d7c4' User entered '10 Oct 2020 18:46'	System	10 Oct 2020 22:46:50
	System	10 Oct 2020 22:46:50

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 4'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:15:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7d7bfb50-d129-497a-9f2e-b9d531fbddc5' User entered 'Yes (Y)'	System	11 Oct 2020 19:16:21
	System	11 Oct 2020 19:16:21

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:15:24', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7d7bfb50-d129-497a-9f2e-b9d531fbddc5' User entered '97.6'	System	11 Oct 2020 19:16:21
	System	11 Oct 2020 19:16:21

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:15:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7d7bfb50-d129-497a-9f2e-b9d531fbddc5'	System	11 Oct 2020 19:16:21
User entered 'No (N)'	System	11 Oct 2020 19:16:21

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:19', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7d7bfb50-d129-497a-9f2e-b9d531fbddc5' User entered '11 Oct 2020 15:16'	System	11 Oct 2020 19:16:21
	System	11 Oct 2020 19:16:21

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 5'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:10', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '320371d8-c1e6-4acd-a2d5-b4af1bcb5e37' User entered 'Yes (Y)'	System	12 Oct 2020 19:39:34
	System	12 Oct 2020 19:39:34

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:20', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '320371d8-c1e6-4acd-a2d5-b4af1bcb5e37' User entered '97.6'	System	12 Oct 2020 19:39:34
	System	12 Oct 2020 19:39:34

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '320371d8-c1e6-4acd-a2d5-b4af1bcb5e37' User entered 'No (N)'	System	12 Oct 2020 19:39:34
	System	12 Oct 2020 19:39:34

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '320371d8-c1e6-4acd-a2d5-b4af1bcb5e37'	System	12 Oct 2020 19:39:34
User entered '12 Oct 2020 15:39'	System	12 Oct 2020 19:39:34

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 6'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:53:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '68782daa-cc01-4c54-9636-e207243919c6' User entered 'Yes (Y)'	System	13 Oct 2020 17:54:25
	System	13 Oct 2020 17:54:25

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:54:05', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '68782daa-cc01-4c54-9636-e207243919c6' User entered '97.8'	System	13 Oct 2020 17:54:25
	System	13 Oct 2020 17:54:25

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:54:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '68782daa-cc01-4c54-9636-e207243919c6' User entered 'No (N)'	System	13 Oct 2020 17:54:25
	System	13 Oct 2020 17:54:25

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:54:21', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '68782daa-cc01-4c54-9636-e207243919c6' User entered '13 Oct 2020 13:54'	System	13 Oct 2020 17:54:25
	System	13 Oct 2020 17:54:25

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 7'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:51:54', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3fd20cf2-45ae-4951-b02c-74b35ea5e98e' User entered 'Yes (Y)'	System	14 Oct 2020 20:52:15
	System	14 Oct 2020 20:52:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3fd20cf2-45ae-4951-b02c-74b35ea5e98e' User entered '97.6'	System	14 Oct 2020 20:52:15
	System	14 Oct 2020 20:52:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:09', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3fd20cf2-45ae-4951-b02c-74b35ea5e98e'	System	14 Oct 2020 20:52:15
User entered 'No (N)'	System	14 Oct 2020 20:52:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3fd20cf2-45ae-4951-b02c-74b35ea5e98e' User entered '14 Oct 2020 16:52'	System	14 Oct 2020 20:52:15
	System	14 Oct 2020 20:52:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3efe889d-cdf1-4837-95c8-ff16572f9a90'	System	08 Oct 2020 14:31:51
User entered 'None (1)'	System	08 Oct 2020 14:31:51

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:33', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3efe889d-cdf1-4837-95c8-ff16572f9a90'	System	08 Oct 2020 14:31:51
User entered 'No (N)'	System	08 Oct 2020 14:31:51

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:38', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3efe889d-cdf1-4837-95c8-ff16572f9a90'	System	08 Oct 2020 14:31:51
User entered 'No (N)'	System	08 Oct 2020 14:31:51

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:44', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3efe889d-cdf1-4837-95c8-ff16572f9a90'	System	08 Oct 2020 14:31:51
User entered 'None (1)'	System	08 Oct 2020 14:31:51

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:48', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3efe889d-cdf1-4837-95c8-ff16572f9a90' User entered '08 Oct 2020 10:31'	System	08 Oct 2020 14:31:51
	System	08 Oct 2020 14:31:51

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 10:16'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 12:46'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:33:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2243642b-3ed9-4d78-90ed-28e947d7fa3e' User entered 'None (1)'	System	08 Oct 2020 21:34:00
	System	08 Oct 2020 21:34:00

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:33:32', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2243642b-3ed9-4d78-90ed-28e947d7fa3e' User entered 'No (N)'	System	08 Oct 2020 21:34:00
	System	08 Oct 2020 21:34:00

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:33:48', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2243642b-3ed9-4d78-90ed-28e947d7fa3e' User entered 'No (N)'	System	08 Oct 2020 21:34:00
	System	08 Oct 2020 21:34:00

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:33:53', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2243642b-3ed9-4d78-90ed-28e947d7fa3e' User entered 'None (1)'	System	08 Oct 2020 21:34:00
	System	08 Oct 2020 21:34:00

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:33:57', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2243642b-3ed9-4d78-90ed-28e947d7fa3e' User entered '08 Oct 2020 17:33'	System	08 Oct 2020 21:34:00
	System	08 Oct 2020 21:34:00

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 13:41'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 2'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:05', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '76f74c8c-01ca-4dd1-847d-f148244a27b6'	System	09 Oct 2020 20:11:36
User entered 'None (1)'	System	09 Oct 2020 20:11:36

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:09', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '76f74c8c-01ca-4dd1-847d-f148244a27b6'	System	09 Oct 2020 20:11:36
User entered 'No (N)'	System	09 Oct 2020 20:11:36

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:14', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '76f74c8c-01ca-4dd1-847d-f148244a27b6' User entered 'No (N)'	System	09 Oct 2020 20:11:36
	System	09 Oct 2020 20:11:36

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:19', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '76f74c8c-01ca-4dd1-847d-f148244a27b6'	System	09 Oct 2020 20:11:36
User entered 'None (1)'	System	09 Oct 2020 20:11:36

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:34', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '76f74c8c-01ca-4dd1-847d-f148244a27b6' User entered '09 Oct 2020 16:11'	System	09 Oct 2020 20:11:36
	System	09 Oct 2020 20:11:36

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 3'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:46:54', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0858fdfa-5ad0-4a1b-bef0-5cea2c219b4d' User entered 'None (1)'	System	10 Oct 2020 22:47:26
	System	10 Oct 2020 22:47:26

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0858fdfa-5ad0-4a1b-bef0-5cea2c219b4d' User entered 'No (N)'	System	10 Oct 2020 22:47:26
	System	10 Oct 2020 22:47:26

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:11', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0858fdfa-5ad0-4a1b-bef0-5cea2c219b4d' User entered 'No (N)'	System	10 Oct 2020 22:47:26
	System	10 Oct 2020 22:47:26

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:16', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0858fdfa-5ad0-4a1b-bef0-5cea2c219b4d' User entered 'None (1)'	System	10 Oct 2020 22:47:26
	System	10 Oct 2020 22:47:26

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:22', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0858fdfa-5ad0-4a1b-bef0-5cea2c219b4d' User entered '10 Oct 2020 18:47'	System	10 Oct 2020 22:47:26
	System	10 Oct 2020 22:47:26

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 4'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:26', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0063841c-6a95-4904-a926-b0ddb253f21a' User entered 'None (1)'	System	11 Oct 2020 19:16:44
	System	11 Oct 2020 19:16:44

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0063841c-6a95-4904-a926-b0ddb253f21a' User entered 'No (N)'	System	11 Oct 2020 19:16:44
	System	11 Oct 2020 19:16:44

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:33', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0063841c-6a95-4904-a926-b0ddb253f21a' User entered 'No (N)'	System	11 Oct 2020 19:16:44
	System	11 Oct 2020 19:16:44

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:37', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0063841c-6a95-4904-a926-b0ddb253f21a' User entered 'None (1)'	System	11 Oct 2020 19:16:44
	System	11 Oct 2020 19:16:44

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:40', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0063841c-6a95-4904-a926-b0ddb253f21a' User entered '11 Oct 2020 15:16'	System	11 Oct 2020 19:16:44
	System	11 Oct 2020 19:16:44

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 5'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:34', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2566158c-81b8-43ae-90f5-072f4e220124' User entered 'None (1)'	System	12 Oct 2020 19:39:54
	System	12 Oct 2020 19:39:54

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:37', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2566158c-81b8-43ae-90f5-072f4e220124' User entered 'No (N)'	System	12 Oct 2020 19:39:54
	System	12 Oct 2020 19:39:54

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:42', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2566158c-81b8-43ae-90f5-072f4e220124' User entered 'No (N)'	System	12 Oct 2020 19:39:54
	System	12 Oct 2020 19:39:54

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:47', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2566158c-81b8-43ae-90f5-072f4e220124' User entered 'None (1)'	System	12 Oct 2020 19:39:54
	System	12 Oct 2020 19:39:54

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:52', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2566158c-81b8-43ae-90f5-072f4e220124' User entered '12 Oct 2020 15:39'	System	12 Oct 2020 19:39:54
	System	12 Oct 2020 19:39:54

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 6'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:54:27', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a62f65aa-c7d9-4bb7-9d34-d602ea8d3202' User entered 'None (1)'	System	13 Oct 2020 17:54:53
	System	13 Oct 2020 17:54:53

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:54:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a62f65aa-c7d9-4bb7-9d34-d602ea8d3202'	System	13 Oct 2020 17:54:53
User entered 'No (N)'	System	13 Oct 2020 17:54:53

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:54:42', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a62f65aa-c7d9-4bb7-9d34-d602ea8d3202' User entered 'No (N)'	System	13 Oct 2020 17:54:53
	System	13 Oct 2020 17:54:53

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:54:46', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a62f65aa-c7d9-4bb7-9d34-d602ea8d3202' User entered 'None (1)'	System	13 Oct 2020 17:54:53
	System	13 Oct 2020 17:54:53

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:54:51', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a62f65aa-c7d9-4bb7-9d34-d602ea8d3202' User entered '13 Oct 2020 13:54'	System	13 Oct 2020 17:54:53
	System	13 Oct 2020 17:54:53

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 7'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:19', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4785603d-a51f-4881-a9aa-0a28547b3939'	System	14 Oct 2020 20:52:40
User entered 'None (1)'	System	14 Oct 2020 20:52:40

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4785603d-a51f-4881-a9aa-0a28547b3939' User entered 'No (N)'	System	14 Oct 2020 20:52:40
	System	14 Oct 2020 20:52:40

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:27', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4785603d-a51f-4881-a9aa-0a28547b3939' User entered 'No (N)'	System	14 Oct 2020 20:52:40
	System	14 Oct 2020 20:52:40

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:31', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4785603d-a51f-4881-a9aa-0a28547b3939' User entered 'None (1)'	System	14 Oct 2020 20:52:40
	System	14 Oct 2020 20:52:40

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:36', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4785603d-a51f-4881-a9aa-0a28547b3939' User entered '14 Oct 2020 16:52'	System	14 Oct 2020 20:52:40
	System	14 Oct 2020 20:52:40

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:31:55', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f3372b72-7311-4a3e-a946-35af2de6ac8f' User entered 'None (0)'	System	08 Oct 2020 14:32:30
	System	08 Oct 2020 14:32:30

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:32:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f3372b72-7311-4a3e-a946-35af2de6ac8f' User entered 'None (0)'	System	08 Oct 2020 14:32:30
	System	08 Oct 2020 14:32:30

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:32:07', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f3372b72-7311-4a3e-a946-35af2de6ac8f' User entered 'None (0)'	System	08 Oct 2020 14:32:30
	System	08 Oct 2020 14:32:30

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:32:10', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f3372b72-7311-4a3e-a946-35af2de6ac8f' User entered 'None (0)'	System	08 Oct 2020 14:32:30
	System	08 Oct 2020 14:32:30

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:32:14', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f3372b72-7311-4a3e-a946-35af2de6ac8f' User entered 'None (0)'	System	08 Oct 2020 14:32:30
	System	08 Oct 2020 14:32:30

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:32:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f3372b72-7311-4a3e-a946-35af2de6ac8f' User entered 'None (0)'	System	08 Oct 2020 14:32:30
	System	08 Oct 2020 14:32:30

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:32:21', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f3372b72-7311-4a3e-a946-35af2de6ac8f' User entered 'No (N)'	System	08 Oct 2020 14:32:30
	System	08 Oct 2020 14:32:30

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T10:32:25', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f3372b72-7311-4a3e-a946-35af2de6ac8f' User entered '08 Oct 2020 10:32'	System	08 Oct 2020 14:32:30
	System	08 Oct 2020 14:32:30

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 10:16'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 12:46'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:34:02', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5d3e09d3-cca7-4408-9335-30df98766fc7' User entered 'None (0)'	System	08 Oct 2020 21:34:36
	System	08 Oct 2020 21:34:36

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:34:05', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5d3e09d3-cca7-4408-9335-30df98766fc7' User entered 'None (0)'	System	08 Oct 2020 21:34:36
	System	08 Oct 2020 21:34:36

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:34:09', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5d3e09d3-cca7-4408-9335-30df98766fc7' User entered 'None (0)'	System	08 Oct 2020 21:34:36
	System	08 Oct 2020 21:34:36

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:34:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5d3e09d3-cca7-4408-9335-30df98766fc7' User entered 'None (0)'	System	08 Oct 2020 21:34:36
	System	08 Oct 2020 21:34:36

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:34:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5d3e09d3-cca7-4408-9335-30df98766fc7' User entered 'None (0)'	System	08 Oct 2020 21:34:36
	System	08 Oct 2020 21:34:36

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:34:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5d3e09d3-cca7-4408-9335-30df98766fc7' User entered 'None (0)'	System	08 Oct 2020 21:34:36
	System	08 Oct 2020 21:34:36

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:34:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5d3e09d3-cca7-4408-9335-30df98766fc7' User entered 'No (N)'	System	08 Oct 2020 21:34:36
	System	08 Oct 2020 21:34:36

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-08T17:34:32', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5d3e09d3-cca7-4408-9335-30df98766fc7' User entered '08 Oct 2020 17:34'	System	08 Oct 2020 21:34:36
	System	08 Oct 2020 21:34:36

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '08 Oct 2020 13:41'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 2'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:39', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c4cb45b6-d893-4639-9869-c7d438f0d8ad' User entered 'None (0)'	System	09 Oct 2020 20:12:21
	System	09 Oct 2020 20:12:21

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:45', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c4cb45b6-d893-4639-9869-c7d438f0d8ad' User entered 'None (0)'	System	09 Oct 2020 20:12:21
	System	09 Oct 2020 20:12:21

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:49', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c4cb45b6-d893-4639-9869-c7d438f0d8ad' User entered 'None (0)'	System	09 Oct 2020 20:12:21
	System	09 Oct 2020 20:12:21

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:54', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c4cb45b6-d893-4639-9869-c7d438f0d8ad' User entered 'None (0)'	System	09 Oct 2020 20:12:21
	System	09 Oct 2020 20:12:21

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:11:58', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c4cb45b6-d893-4639-9869-c7d438f0d8ad' User entered 'None (0)'	System	09 Oct 2020 20:12:21
	System	09 Oct 2020 20:12:21

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:12:02', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c4cb45b6-d893-4639-9869-c7d438f0d8ad' User entered 'None (0)'	System	09 Oct 2020 20:12:21
	System	09 Oct 2020 20:12:21

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:12:12', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c4cb45b6-d893-4639-9869-c7d438f0d8ad' User entered 'No (N)'	System	09 Oct 2020 20:12:21
	System	09 Oct 2020 20:12:21

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-09T16:12:20', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'c4cb45b6-d893-4639-9869-c7d438f0d8ad' User entered '09 Oct 2020 16:12'	System	09 Oct 2020 20:12:21
	System	09 Oct 2020 20:12:21

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 3'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:31', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0177c275-b0d3-480d-ac5a-f31e2adeca58' User entered 'None (0)'	System	10 Oct 2020 22:48:05
	System	10 Oct 2020 22:48:05

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:34', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0177c275-b0d3-480d-ac5a-f31e2adeca58' User entered 'None (0)'	System	10 Oct 2020 22:48:05
	System	10 Oct 2020 22:48:05

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:38', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0177c275-b0d3-480d-ac5a-f31e2adeca58' User entered 'None (0)'	System	10 Oct 2020 22:48:05
	System	10 Oct 2020 22:48:05

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:43', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0177c275-b0d3-480d-ac5a-f31e2adeca58' User entered 'None (0)'	System	10 Oct 2020 22:48:05
	System	10 Oct 2020 22:48:05

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:47', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0177c275-b0d3-480d-ac5a-f31e2adeca58' User entered 'None (0)'	System	10 Oct 2020 22:48:05
	System	10 Oct 2020 22:48:05

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:51', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0177c275-b0d3-480d-ac5a-f31e2adeca58' User entered 'None (0)'	System	10 Oct 2020 22:48:05
	System	10 Oct 2020 22:48:05

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:47:55', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0177c275-b0d3-480d-ac5a-f31e2adeca58' User entered 'No (N)'	System	10 Oct 2020 22:48:05
	System	10 Oct 2020 22:48:05

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-10T18:48:02', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0177c275-b0d3-480d-ac5a-f31e2adeca58' User entered '10 Oct 2020 18:48'	System	10 Oct 2020 22:48:05
	System	10 Oct 2020 22:48:05

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 4'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:45', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9815b0c6-9570-4551-a796-e67a7f042e08' User entered 'None (0)'	System	11 Oct 2020 19:17:26
	System	11 Oct 2020 19:17:26

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:50', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9815b0c6-9570-4551-a796-e67a7f042e08' User entered 'None (0)'	System	11 Oct 2020 19:17:26
	System	11 Oct 2020 19:17:26

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:16:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9815b0c6-9570-4551-a796-e67a7f042e08' User entered 'None (0)'	System	11 Oct 2020 19:17:26
	System	11 Oct 2020 19:17:26

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:17:04', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9815b0c6-9570-4551-a796-e67a7f042e08' User entered 'None (0)'	System	11 Oct 2020 19:17:26
	System	11 Oct 2020 19:17:26

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:17:07', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9815b0c6-9570-4551-a796-e67a7f042e08' User entered 'None (0)'	System	11 Oct 2020 19:17:26
	System	11 Oct 2020 19:17:26

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:17:10', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9815b0c6-9570-4551-a796-e67a7f042e08' User entered 'None (0)'	System	11 Oct 2020 19:17:26
	System	11 Oct 2020 19:17:26

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:17:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9815b0c6-9570-4551-a796-e67a7f042e08' User entered 'No (N)'	System	11 Oct 2020 19:17:26
	System	11 Oct 2020 19:17:26

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-11T15:17:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '9815b0c6-9570-4551-a796-e67a7f042e08' User entered '11 Oct 2020 15:17'	System	11 Oct 2020 19:17:26
	System	11 Oct 2020 19:17:26

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 5'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:39:58', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3c199fb9-ec02-4075-a711-8e54e68a8f91' User entered 'None (0)'	System	12 Oct 2020 19:40:40
	System	12 Oct 2020 19:40:40

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:40:01', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3c199fb9-ec02-4075-a711-8e54e68a8f91' User entered 'None (0)'	System	12 Oct 2020 19:40:40
	System	12 Oct 2020 19:40:40

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:40:06', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3c199fb9-ec02-4075-a711-8e54e68a8f91' User entered 'None (0)'	System	12 Oct 2020 19:40:40
	System	12 Oct 2020 19:40:40

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:40:09', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3c199fb9-ec02-4075-a711-8e54e68a8f91' User entered 'None (0)'	System	12 Oct 2020 19:40:40
	System	12 Oct 2020 19:40:40

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:40:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3c199fb9-ec02-4075-a711-8e54e68a8f91' User entered 'None (0)'	System	12 Oct 2020 19:40:40
	System	12 Oct 2020 19:40:40

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:40:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3c199fb9-ec02-4075-a711-8e54e68a8f91' User entered 'None (0)'	System	12 Oct 2020 19:40:40
	System	12 Oct 2020 19:40:40

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:40:26', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3c199fb9-ec02-4075-a711-8e54e68a8f91' User entered 'No (N)'	System	12 Oct 2020 19:40:40
	System	12 Oct 2020 19:40:40

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-12T15:40:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '3c199fb9-ec02-4075-a711-8e54e68a8f91' User entered '12 Oct 2020 15:40'	System	12 Oct 2020 19:40:40
	System	12 Oct 2020 19:40:40

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 6'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:55:01', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7b8a715e-ee20-43e0-b462-2d532299a16b' User entered 'None (0)'	System	13 Oct 2020 17:55:42
	System	13 Oct 2020 17:55:42

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:55:10', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7b8a715e-ee20-43e0-b462-2d532299a16b' User entered 'None (0)'	System	13 Oct 2020 17:55:42
	System	13 Oct 2020 17:55:42

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:55:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7b8a715e-ee20-43e0-b462-2d532299a16b' User entered 'None (0)'	System	13 Oct 2020 17:55:42
	System	13 Oct 2020 17:55:42

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:55:24', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7b8a715e-ee20-43e0-b462-2d532299a16b' User entered 'None (0)'	System	13 Oct 2020 17:55:42
	System	13 Oct 2020 17:55:42

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:55:29', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7b8a715e-ee20-43e0-b462-2d532299a16b' User entered 'None (0)'	System	13 Oct 2020 17:55:42
	System	13 Oct 2020 17:55:42

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:55:32', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7b8a715e-ee20-43e0-b462-2d532299a16b' User entered 'None (0)'	System	13 Oct 2020 17:55:42
	System	13 Oct 2020 17:55:42

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:55:37', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7b8a715e-ee20-43e0-b462-2d532299a16b' User entered 'No (N)'	System	13 Oct 2020 17:55:42
	System	13 Oct 2020 17:55:42

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-13T13:55:40', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '7b8a715e-ee20-43e0-b462-2d532299a16b' User entered '13 Oct 2020 13:55'	System	13 Oct 2020 17:55:42
	System	13 Oct 2020 17:55:42

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	08 Oct 2020 14:05:15
User entered 'Day 7'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:43', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f85b9050-74b9-4763-b2a1-7d627f7cb4bb' User entered 'None (0)'	System	14 Oct 2020 20:53:18
	System	14 Oct 2020 20:53:18

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:49', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f85b9050-74b9-4763-b2a1-7d627f7cb4bb' User entered 'None (0)'	System	14 Oct 2020 20:53:18
	System	14 Oct 2020 20:53:18

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:52', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f85b9050-74b9-4763-b2a1-7d627f7cb4bb' User entered 'None (0)'	System	14 Oct 2020 20:53:18
	System	14 Oct 2020 20:53:18

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:55', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f85b9050-74b9-4763-b2a1-7d627f7cb4bb' User entered 'None (0)'	System	14 Oct 2020 20:53:18
	System	14 Oct 2020 20:53:18

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:52:58', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f85b9050-74b9-4763-b2a1-7d627f7cb4bb' User entered 'None (0)'	System	14 Oct 2020 20:53:18
	System	14 Oct 2020 20:53:18

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:53:01', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f85b9050-74b9-4763-b2a1-7d627f7cb4bb' User entered 'None (0)'	System	14 Oct 2020 20:53:18
	System	14 Oct 2020 20:53:18

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:53:10', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f85b9050-74b9-4763-b2a1-7d627f7cb4bb' User entered 'No (N)'	System	14 Oct 2020 20:53:18
	System	14 Oct 2020 20:53:18

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-10-14T16:53:14', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f85b9050-74b9-4763-b2a1-7d627f7cb4bb' User entered '14 Oct 2020 16:53'	System	14 Oct 2020 20:53:18
	System	14 Oct 2020 20:53:18

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 14:05:15

US3532276

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:08:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 14:05:15

US3532276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	15 Oct 2020 19:31:25

US3532276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered '15 Oct 2020'	Lisa Macoy (b) (4)	15 Oct 2020 19:31:25

US3532276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	15 Oct 2020 19:31:25

US3532276

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered empty.	Lisa Macoy (b) (4)	15 Oct 2020 19:31:25

US3532276

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	22 Feb 2021 11:09:55
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	15 Oct 2020 19:31:30

US3532276

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'I'	System	15 Oct 2020 19:31:30

US3532276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	23 Oct 2020 17:23:31

US3532276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '23 Oct 2020'	Lisa Macoy (b) (4)	23 Oct 2020 17:23:31

US3532276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	23 Oct 2020 17:23:31

US3532276

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	23 Oct 2020 17:23:31

US3532276

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	23 Oct 2020 17:23:35

US3532276

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'I'	System	23 Oct 2020 17:23:35

US3532276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	30 Oct 2020 16:34:10

US3532276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '30 Oct 2020'	Lisa Macoy (b) (4)	30 Oct 2020 16:34:10

US3532276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	30 Oct 2020 16:34:10

US3532276

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 16:34:10

US3532276

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	30 Oct 2020 16:34:29

US3532276

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'I'	System	30 Oct 2020 16:34:29

US3532276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	05 Nov 2020 17:05:03

US3532276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '5 Nov 2020'	Lisa Macoy (b) (4)	05 Nov 2020 17:05:03

US3532276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	05 Nov 2020 17:05:03

US3532276

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'VISIT3'	System	05 Nov 2020 17:05:03

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 10:55:30
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'done' (Site from DM).	Kathy Stephens (b) (4) (b) (4)	12 Nov 2020 14:52:01
User entered '05 Nov 2020' reason for change: Data Entry Error	Kathy Stephens (b) (4) (b) (4)	12 Nov 2020 14:51:56
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 11:48:39
User entered '5 Nov 2020'	Lisa Macoy (b) (4) (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '11:59'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered '05 Nov 2020 11:59'	System	12 Nov 2020 14:51:56
User entered '5 Nov 2020 11:59'	System	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '98' F	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '65'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'bpm'	System	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '20'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'breaths/min'	System	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '125'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'mmHg'	System	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '78'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'mmHg'	System	05 Nov 2020 19:05:32

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08

US3532276

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08

US3532276

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'No (N)'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:38

US3532276

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered empty.	Lisa Macoy (b) (4)	05 Nov 2020 19:05:38

US3532276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:48

US3532276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '5 Nov 2020'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:48

US3532276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered '12:02'	Lisa Macoy (b) (4)	05 Nov 2020 19:05:48

US3532276

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered '5 Nov 2020 12:02'	System	05 Nov 2020 19:05:48

US3532276

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User signature succeeded.	Evan Anderson (b) (4)	12 Feb 2021 20:29:56
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	05 Nov 2020 17:05:09

US3532276

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 02:02:08
User entered 'I'	System	05 Nov 2020 17:05:09

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 64'	System	10 Sep 2020 16:14:52

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-10T03:19:46', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'da4c0132-7cbf-433c-9cdb-56182e7cb39f' User entered 'No (N)'	System	10 Nov 2020 08:20:22
	System	10 Nov 2020 08:20:22

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-10T03:19:55', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'da4c0132-7cbf-433c-9cdb-56182e7cb39f' User entered 'No (N)'	System	10 Nov 2020 08:20:22
	System	10 Nov 2020 08:20:22

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-10T03:20:16', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'da4c0132-7cbf-433c-9cdb-56182e7cb39f' User entered '10 Nov 2020 03:20:16'	System	10 Nov 2020 08:20:22
	System	10 Nov 2020 08:20:22

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 16:14:52

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered 'Day 71'	System	10 Sep 2020 16:14:52

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-17T07:25:48', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7c883b-1e3a-48b4-b314-0c7a24bf76cf' User entered 'No (N)'	System	17 Nov 2020 12:34:20
	System	17 Nov 2020 12:34:20

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-17T07:25:53', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7c883b-1e3a-48b4-b314-0c7a24bf76cf' User entered 'No (N)'	System	17 Nov 2020 12:34:20
	System	17 Nov 2020 12:34:20

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-17T07:25:58', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7c883b-1e3a-48b4-b314-0c7a24bf76cf' User entered '17 Nov 2020 07:25:58'	System	17 Nov 2020 12:34:20
	System	17 Nov 2020 12:34:20

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 16:14:52

US3532276

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 05:45:03
Data entry locked.	System	10 Sep 2020 16:14:52
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 16:14:52

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-24T07:39:54', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0315416a-d909-45b6-90f4-deb22e0fd766'	System	24 Nov 2020 12:40:14
User entered 'No (N)'	System	24 Nov 2020 12:40:14

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-24T07:40:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0315416a-d909-45b6-90f4-deb22e0fd766'	System	24 Nov 2020 12:40:14
User entered 'No (N)'	System	24 Nov 2020 12:40:14

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-24T07:40:12', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0315416a-d909-45b6-90f4-deb22e0fd766' User entered '24 Nov 2020 07:40:12'	System	24 Nov 2020 12:40:14
	System	24 Nov 2020 12:40:14

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-29T10:15:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f607820d-a158-4899-8aa3-e92e4f418206' User entered 'No (N)'	System	29 Nov 2020 15:15:16
	System	29 Nov 2020 15:15:16

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-29T10:15:08', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f607820d-a158-4899-8aa3-e92e4f418206'	System	29 Nov 2020 15:15:16
User entered 'No (N)'	System	29 Nov 2020 15:15:16

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-11-29T10:15:11', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'f607820d-a158-4899-8aa3-e92e4f418206' User entered '29 Nov 2020 10:15:11'	System	29 Nov 2020 15:15:16
	System	29 Nov 2020 15:15:16

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-05T07:36:57', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4d9a4643-cfed-43fe-a81a-70fdb64e28e4' User entered 'No (N)'	System	05 Dec 2020 12:37:08
	System	05 Dec 2020 12:37:08

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-05T07:37:03', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4d9a4643-cfed-43fe-a81a-70fdb64e28e4' User entered 'No (N)'	System	05 Dec 2020 12:37:08
	System	05 Dec 2020 12:37:08

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-05T07:37:07', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4d9a4643-cfed-43fe-a81a-70fdb64e28e4' User entered '05 Dec 2020 07:37:07'	System	05 Dec 2020 12:37:08
	System	05 Dec 2020 12:37:08

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-12T07:57:19', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5f64b7df-32b0-4e66-8180-12bbc987b832' User entered 'No (N)'	System	12 Dec 2020 12:57:37
	System	12 Dec 2020 12:57:37

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-12T07:57:28', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5f64b7df-32b0-4e66-8180-12bbc987b832'	System	12 Dec 2020 12:57:37
User entered 'No (N)'	System	12 Dec 2020 12:57:37

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-12T07:57:34', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5f64b7df-32b0-4e66-8180-12bbc987b832' User entered '12 Dec 2020 07:57:34'	System	12 Dec 2020 12:57:37
	System	12 Dec 2020 12:57:37

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-19T11:39:01', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0a1588d5-6ce0-4317-bb8b-571e8bef7d6e' User entered 'No (N)'	System	19 Dec 2020 16:39:20
	System	19 Dec 2020 16:39:20

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-19T11:39:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0a1588d5-6ce0-4317-bb8b-571e8bef7d6e' User entered 'No (N)'	System	19 Dec 2020 16:39:20
	System	19 Dec 2020 16:39:20

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-19T11:39:18', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0a1588d5-6ce0-4317-bb8b-571e8bef7d6e' User entered '19 Dec 2020 11:39:18'	System	19 Dec 2020 16:39:20
	System	19 Dec 2020 16:39:20

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-26T08:34:24', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4f3b8ba4-a8ce-412f-aa9f-5de65d1f7b81' User entered 'No (N)'	System	26 Dec 2020 13:34:38
	System	26 Dec 2020 13:34:38

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-26T08:34:31', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4f3b8ba4-a8ce-412f-aa9f-5de65d1f7b81' User entered 'No (N)'	System	26 Dec 2020 13:34:38

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2020-12-26T08:34:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '4f3b8ba4-a8ce-412f-aa9f-5de65d1f7b81' User entered '26 Dec 2020 08:34:35'	System	26 Dec 2020 13:34:38
	System	26 Dec 2020 13:34:38

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-02T18:13:37', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '570f0c3c-a41e-49cc-9242-bc56f0ac732e' User entered 'No (N)'	System	02 Jan 2021 23:13:49
	System	02 Jan 2021 23:13:49

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-02T18:13:42', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '570f0c3c-a41e-49cc-9242-bc56f0ac732e'	System	02 Jan 2021 23:13:49
User entered 'No (N)'	System	02 Jan 2021 23:13:49

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-02T18:13:46', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '570f0c3c-a41e-49cc-9242-bc56f0ac732e' User entered '02 Jan 2021 18:13:46'	System	02 Jan 2021 23:13:49
	System	02 Jan 2021 23:13:49

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-09T16:29:43', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dead12b4-f544-48fa-a687-314ac5c8d77f' User entered 'Yes (Y)'	System	09 Jan 2021 21:29:56
	System	09 Jan 2021 21:29:56

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-09T16:28:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dead12b4-f544-48fa-a687-314ac5c8d77f' User entered 'No (N)'	System	09 Jan 2021 21:29:56

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-09T16:28:56', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dead12b4-f544-48fa-a687-314ac5c8d77f' User entered 'No (N)'	System	09 Jan 2021 21:29:56
	System	09 Jan 2021 21:29:56

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-09T16:29:05', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dead12b4-f544-48fa-a687-314ac5c8d77f' User entered 'No (N)'	System	09 Jan 2021 21:29:56
	System	09 Jan 2021 21:29:56

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-09T16:29:53', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dead12b4-f544-48fa-a687-314ac5c8d77f' User entered '09 Jan 2021 16:29:53'	System	09 Jan 2021 21:29:56
	System	09 Jan 2021 21:29:56

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-16T08:53:16', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5b5cde05-4b8c-474a-b94c-a92129e5a3f6'	System	16 Jan 2021 13:54:24
User entered 'Yes (Y)'	System	16 Jan 2021 13:54:24

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-16T08:53:24', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5b5cde05-4b8c-474a-b94c-a92129e5a3f6'	System	16 Jan 2021 13:54:24
User entered 'No (N)'	System	16 Jan 2021 13:54:24

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-16T08:53:38', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5b5cde05-4b8c-474a-b94c-a92129e5a3f6'	System	16 Jan 2021 13:54:24
User entered 'No (N)'	System	16 Jan 2021 13:54:24

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-16T08:54:15', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5b5cde05-4b8c-474a-b94c-a92129e5a3f6'	System	16 Jan 2021 13:54:24
User entered 'No (N)'	System	16 Jan 2021 13:54:24

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-16T08:54:23', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '5b5cde05-4b8c-474a-b94c-a92129e5a3f6' User entered '16 Jan 2021 08:54:23'	System	16 Jan 2021 13:54:24
	System	16 Jan 2021 13:54:24

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:09:39', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered 'Yes (Y)'	System	23 Jan 2021 13:11:11
	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:09:48', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466'	System	23 Jan 2021 13:11:11
User entered 'Yes (Y)'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:01', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466'	System	23 Jan 2021 13:11:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:09', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered 'Yes (Y)'	System	23 Jan 2021 13:11:11
	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '1'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '1'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '1'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:30', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466' User entered '0'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:34', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466'	System	23 Jan 2021 13:11:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:40', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466'	System	23 Jan 2021 13:11:11
User entered 'Yes (Y)'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:45', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466'	System	23 Jan 2021 13:11:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-23T08:10:58', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fd78a904-1471-4291-9aa4-d7972b0ec466'	System	23 Jan 2021 13:11:11
User entered '23 Jan 2021 08:10:58'	System	23 Jan 2021 13:11:11

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-30T11:30:27', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'febe07e3-c77e-41a3-bcb1-ddf33b5e6aa8' User entered 'No (N)'	System	03 Feb 2021 16:06:08
	System	03 Feb 2021 16:06:08

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-30T11:30:35', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'febe07e3-c77e-41a3-bcb1-ddf33b5e6aa8' User entered 'No (N)'	System	03 Feb 2021 16:06:08

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-01-30T11:30:39', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'febe07e3-c77e-41a3-bcb1-ddf33b5e6aa8' User entered '30 Jan 2021 11:30:39'	System	03 Feb 2021 16:06:08
	System	03 Feb 2021 16:06:08

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-06T10:24:43', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fb21f231-8d6a-4408-bab0-91bb1ffc256b' User entered 'No (N)'	System	06 Feb 2021 15:24:51
	System	06 Feb 2021 15:24:51

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-06T10:24:39', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fb21f231-8d6a-4408-bab0-91bb1ffc256b' User entered 'No (N)'	System	06 Feb 2021 15:24:51

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-06T10:24:48', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'fb21f231-8d6a-4408-bab0-91bb1ffc256b' User entered '06 Feb 2021 10:24:48'	System	06 Feb 2021 15:24:51
	System	06 Feb 2021 15:24:51

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:03:53', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered 'Yes (Y)'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:04:12', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered 'Yes (Y)'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:04:20', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c'	System	13 Feb 2021 12:05:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:04:26', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered 'Yes (Y)'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '1'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '1'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '1'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '1'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '1'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '0'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:04', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c'	System	13 Feb 2021 12:05:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:13', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered 'Yes (Y)'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:17', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c'	System	13 Feb 2021 12:05:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-13T07:05:29', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '6e7ca4b5-3302-433f-bf01-17818eb7063c' User entered '13 Feb 2021 07:05:29'	System	13 Feb 2021 12:05:40
	System	13 Feb 2021 12:05:40

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-21T16:47:04', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2f512d7f-d1bf-4f63-a586-8f4d37d13bf7' User entered 'No (N)'	System	21 Feb 2021 21:47:16
	System	21 Feb 2021 21:47:16

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-21T16:47:09', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2f512d7f-d1bf-4f63-a586-8f4d37d13bf7' User entered 'No (N)'	System	21 Feb 2021 21:47:16

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-21T16:47:14', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '2f512d7f-d1bf-4f63-a586-8f4d37d13bf7' User entered '21 Feb 2021 16:47:14'	System	21 Feb 2021 21:47:16
	System	21 Feb 2021 21:47:16

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-27T07:29:26-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '014f2adf-ccc1-44f9-b17b-cbcdab480d16'	System	27 Feb 2021 12:29:41
User entered 'No (N)'	System	27 Feb 2021 12:29:41

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-27T07:29:31-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '014f2adf-ccc1-44f9-b17b-cbcdab480d16'	System	27 Feb 2021 12:29:41
User entered 'No (N)'	System	27 Feb 2021 12:29:41

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-27T07:29:38-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '014f2adf-ccc1-44f9-b17b-cbcdab480d16'	System	27 Feb 2021 12:29:41
User entered '27 Feb 2021 12:29:38'	System	27 Feb 2021 12:29:41

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:10:06-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb'	System	06 Mar 2021 14:11:59
User entered 'Yes (Y)'	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:10:24-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered 'Yes (Y)'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:10:32-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb'	System	06 Mar 2021 14:11:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:10:59-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered 'Yes (Y)'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '1'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '1'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '1'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:23-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '0'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:27-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb'	System	06 Mar 2021 14:11:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:33-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered 'Yes (Y)'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:38-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb'	System	06 Mar 2021 14:11:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-06T09:11:48-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '238dfe7a-5bb0-4d82-a46a-1c319f94b5fb' User entered '06 Mar 2021 09:11:48'	System	06 Mar 2021 14:11:59
	System	06 Mar 2021 14:11:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-13T08:38:56-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a92cabef-54d3-47f3-bf81-74860d414a11'	System	13 Mar 2021 13:39:15
User entered 'No (N)'	System	13 Mar 2021 13:39:15

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-13T08:39:05-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a92cabef-54d3-47f3-bf81-74860d414a11'	System	13 Mar 2021 13:39:15
User entered 'No (N)'	System	13 Mar 2021 13:39:15

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-13T08:39:13-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a92cabef-54d3-47f3-bf81-74860d414a11'	System	13 Mar 2021 13:39:15
User entered '13 Mar 2021 08:39:13'	System	13 Mar 2021 13:39:15

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-22T12:00:43-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0d432577-8c8e-4f6f-a0aa-2947d202b5ac'	System	22 Mar 2021 16:02:59
User entered 'No (N)'	System	22 Mar 2021 16:02:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-22T12:00:47-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0d432577-8c8e-4f6f-a0aa-2947d202b5ac'	System	22 Mar 2021 16:02:59
User entered 'No (N)'	System	22 Mar 2021 16:02:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-22T12:00:52-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '0d432577-8c8e-4f6f-a0aa-2947d202b5ac'	System	22 Mar 2021 16:02:59
User entered '22 Mar 2021 12:00:52'	System	22 Mar 2021 16:02:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-27T07:19:48-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dfe76c73-f242-48a7-afac-9496285ed58f' User entered 'No (N)'	System	27 Mar 2021 11:20:09
	System	27 Mar 2021 11:20:09

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-27T07:19:56-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dfe76c73-f242-48a7-afac-9496285ed58f'	System	27 Mar 2021 11:20:09
User entered 'No (N)'	System	27 Mar 2021 11:20:09

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-03-27T07:20:03-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'dfe76c73-f242-48a7-afac-9496285ed58f' User entered '27 Mar 2021 07:20:03'	System	27 Mar 2021 11:20:09
	System	27 Mar 2021 11:20:09

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-03T07:16:01-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a99ef7ce-1694-486a-b41a-a6e70ac0405a'	System	03 Apr 2021 11:16:17
User entered 'No (N)'	System	03 Apr 2021 11:16:17

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-03T07:16:10-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a99ef7ce-1694-486a-b41a-a6e70ac0405a'	System	03 Apr 2021 11:16:17
User entered 'No (N)'	System	03 Apr 2021 11:16:17

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-03T07:16:15-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'a99ef7ce-1694-486a-b41a-a6e70ac0405a'	System	03 Apr 2021 11:16:17
User entered '03 Apr 2021 07:16:15'	System	03 Apr 2021 11:16:17

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-10T07:47:14-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ed262001-0d28-4c30-9e25-9104b7c0f6a2'	System	10 Apr 2021 11:47:24
User entered 'No (N)'	System	10 Apr 2021 11:47:24

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-10T07:47:18-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ed262001-0d28-4c30-9e25-9104b7c0f6a2'	System	10 Apr 2021 11:47:24
User entered 'No (N)'	System	10 Apr 2021 11:47:24

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-10T07:47:22-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'ed262001-0d28-4c30-9e25-9104b7c0f6a2' User entered '10 Apr 2021 07:47:22'	System	10 Apr 2021 11:47:24
	System	10 Apr 2021 11:47:24

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-17T04:07:42-07:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'b4d4eb5e-fac6-49ea-9004-423efbe2c200'	System	17 Apr 2021 11:07:59
User entered 'No (N)'	System	17 Apr 2021 11:07:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-17T04:07:50-07:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'b4d4eb5e-fac6-49ea-9004-423efbe2c200'	System	17 Apr 2021 11:07:59
User entered 'No (N)'	System	17 Apr 2021 11:07:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-17T04:07:53-07:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: 'b4d4eb5e-fac6-49ea-9004-423efbe2c200'	System	17 Apr 2021 11:07:59
User entered '17 Apr 2021 04:07:53'	System	17 Apr 2021 11:07:59

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-24T09:20:50-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '15f94038-4833-4a51-bc28-9a5237ec4430' User entered 'No (N)'	System	24 Apr 2021 13:21:04
	System	24 Apr 2021 13:21:04

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-24T09:20:54-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '15f94038-4833-4a51-bc28-9a5237ec4430' User entered 'No (N)'	System	24 Apr 2021 13:21:04

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-04-24T09:20:59-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '15f94038-4833-4a51-bc28-9a5237ec4430'	System	24 Apr 2021 13:21:04
User entered '24 Apr 2021 09:20:59'	System	24 Apr 2021 13:21:04

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-05-01T06:01:01-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '481ad69c-a36d-403f-aa56-cb1f03e4ef75'	System	01 May 2021 10:01:14
User entered 'No (N)'	System	01 May 2021 10:01:14

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

Have you been exposed to someone with 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 (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-05-01T06:01:08-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '481ad69c-a36d-403f-aa56-cb1f03e4ef75'	System	01 May 2021 10:01:14
User entered 'No (N)'	System	01 May 2021 10:01:14

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-05-01T06:01:12-04:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '481ad69c-a36d-403f-aa56-cb1f03e4ef75'	System	01 May 2021 10:01:14
User entered '01 May 2021 06:01:12'	System	01 May 2021 10:01:14

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:02:21

US3532276

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:08:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:02:21
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:02:21

US3532276

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:08:32

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 10:15:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-27T07:29:07-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '266628d6-0113-46a4-b3dd-6a83d359bdcc'	System	27 Feb 2021 12:29:18
User entered 'No (N)'	System	27 Feb 2021 12:29:18

US3532276

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:08:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:15:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (35F2E918-0ABC-43A8-A056-EA9E71B7E1FE)', Time: '2021-02-27T07:29:14-05:00', User OID: 'PatientReportedOutcome (US3532276)', ODM File OID: '266628d6-0113-46a4-b3dd-6a83d359bdcc'	System	27 Feb 2021 12:29:18
User entered '27 Feb 2021 12:29:14'	System	27 Feb 2021 12:29:18

US3532276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:46:02
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Dec 2020 15:33:52

US3532276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:46:02
User entered '3 Dec 2020'	Lisa Macoy (b) (4)	03 Dec 2020 15:33:52

US3532276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:46:02
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	03 Dec 2020 15:33:52

US3532276

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:46:02
User entered empty.	Lisa Macoy (b) (4)	03 Dec 2020 15:33:52

US3532276

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User signature succeeded.	Evan Anderson (b) (4)	25 Mar 2021 17:46:02
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Dec 2020 15:33:57

US3532276

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:45:48
User entered 'I'	System	03 Dec 2020 15:33:57

US3532276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	31 Jan 2021 20:06:12

US3532276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '5 Jan 2021'	Lisa Macoy (b) (4)	31 Jan 2021 20:06:12

US3532276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	31 Jan 2021 20:06:12

US3532276

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	31 Jan 2021 20:06:12

US3532276

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	31 Jan 2021 20:06:23

US3532276

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User entered 'I'	System	31 Jan 2021 20:06:23

US3532276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 16:10:13

US3532276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '3 Feb 2021'	Lisa Macoy (b) (4)	03 Feb 2021 16:10:13

US3532276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	03 Feb 2021 16:10:13

US3532276

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:10:13

US3532276

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 16:10:21

US3532276

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User entered 'I'	System	03 Feb 2021 16:10:21

US3532276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	04 Mar 2021 17:36:59

US3532276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '4 Mar 2021'	Lisa Macoy (b) (4)	04 Mar 2021 17:36:59

US3532276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	04 Mar 2021 17:36:59

US3532276

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 17:36:59

US3532276

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	04 Mar 2021 17:36:47

US3532276

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:13:41
User entered 'I'	System	04 Mar 2021 17:36:47

US3532276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	07 Apr 2021 14:04:17
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '7 Apr 2021'	Lisa Macoy (b) (4)	07 Apr 2021 14:04:17
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	07 Apr 2021 14:04:17
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User entered 'VISIT4'	System	07 Apr 2021 14:04:17

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User entered empty.	System	07 Apr 2021 14:04:27

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User entered empty.	System	07 Apr 2021 14:04:27

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User entered empty.	System	07 Apr 2021 14:04:27

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User entered empty.	System	07 Apr 2021 14:04:27

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:27
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User entered empty.	System	07 Apr 2021 14:04:27

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59

US3532276

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59

US3532276

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	07 Apr 2021 14:04:34
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	07 Apr 2021 14:04:34
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	07 Apr 2021 14:08:46
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '7 Apr 2021'	Lisa Macoy (b) (4)	07 Apr 2021 14:08:46
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 14:08:57
User entered '09:58' reason for change: Data Entry Error	Lisa Macoy (b) (4)	07 Apr 2021 14:08:57
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 14:08:46
User entered '09:' (non-conformant).	Lisa Macoy (b) (4)	07 Apr 2021 14:08:46
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User entered '7 Apr 2021 09:58'	System	07 Apr 2021 14:08:57
User entered '7 Apr 2021 09:' (non-conformant).	System	07 Apr 2021 14:08:46

US3532276

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	07 Apr 2021 14:09:06
	(b) (4)	

US3532276

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:37:59
User entered 'I'	System	07 Apr 2021 14:09:06

US3532276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	03 May 2021 16:27:16
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	03 May 2021 15:40:39

US3532276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 16:27:16
	(b) (4)	
User entered '3 May 2021'	Lisa Macoy (b) (4)	03 May 2021 15:40:39
	(b) (4)	

US3532276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 16:27:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	03 May 2021 15:40:39

US3532276

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 16:27:16
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 May 2021 15:40:39
	(b) (4)	

US3532276

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	03 May 2021 16:27:16
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	03 May 2021 15:40:44

US3532276

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 15:40:44

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:08:32

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:42
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '19 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:09

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:08:32

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:42
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '15:00'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:09

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:08:32

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:42
User entered '19 Jan 2021 15:00'	System	20 Jan 2021 11:26:09

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:08:32

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:42
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:09

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:08:32

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:42
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:09

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 1 (Day 1)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '09 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:28:34
User entered '05 Jan 2021'	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:26:58
	(b) (4)	

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Jan 2021 11:28:34
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	20 Jan 2021 11:26:58
	(b) (4)	

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:28:34
User entered 'None (None)'	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:26:58
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:28:34
User entered 'None (None)'	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:26:58
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:26:58

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 2 (Day 2)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:28:46
User entered '06 Jan 2021'	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:27:26
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Jan 2021 11:28:46
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	20 Jan 2021 11:27:26
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:26

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 3 (Day 3)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:29:07
User entered '07 Jan 2021'	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:27:42
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:27:42

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Jan 2021 11:29:07
User entered 'Mild (Mild)'	Laila Hussaini (b) (4)	20 Jan 2021 11:27:42
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:27:42

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 4 (Day 4)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '12 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:29:37

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 5 (Day 5)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '13 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:30:10
User entered 'None (None)'	(b) (4)	
	Laila Hussaini (b) (4)	20 Jan 2021 11:30:02
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:02

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 6 (Day 6)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '14 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:30:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 7 (Day 7)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '15 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:15

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 8 (Day 8)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '16 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:31:33

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:33

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 9 (Day 9)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '17 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:31:59

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 10 (Day 10)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '18 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:32:23

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 11 (Day 11)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '19 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '95'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '97.1' F	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:31

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 12 (Day 12)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '20 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '94'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	20 Jan 2021 14:16:21

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '97.5' F	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Severe (Severe)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Moderate (Moderate)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 14:16:21

US3532276

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 13 (Day 13)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '21 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '97'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	21 Jan 2021 15:37:56

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '97.7' F	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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Form: Symptom Log (13)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

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Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:37:56

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Day 14 (Day 14)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '22 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '0'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '60'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User entered '%'	System	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '93' F	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Mild (Mild)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

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Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 08:08:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:49
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'None (None)'	(b) (4) Laila Hussaini (b) (4)	22 Jan 2021 14:56:32

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '19 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:50

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:50

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
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	23 Jan 2021 14:36:05
User entered 'No (N)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	23 Jan 2021 14:36:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Jan 2021 11:33:50
	Laila Hussaini (b) (4)	20 Jan 2021 11:33:50
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '19 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:50

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:50

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:50
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'No (N)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:50

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:50

US3532276

Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:33:50
	(b) (4)	

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Folder: Covid-19 Assessment 19 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 08:08:32

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:49:56
User entered '0'	System	23 Jan 2021 14:36:05

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:08:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User accepted default value 'Day 3 (Day 3)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:08:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 08:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 06:20:51
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Barcode #: 1F618973924, resulted already received. ' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	02 Feb 2021 20:02:34
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:58:12
User entered '21 Jan 2021'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:08:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User accepted default value 'Day 5 (Day 5)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:08:32

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
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	23 Jan 2021 14:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	System	23 Jan 2021 14:36:18
User opened query 'Data is required. Please complete.' (Site from System).	Laila Hussaini (b) (4)	23 Jan 2021 14:36:18
User entered empty.	(b) (4)	
	System	21 Jan 2021 15:38:06
	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 08:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:08:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User accepted default value 'Day 7 (Day 7)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:08:32

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
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	23 Jan 2021 14:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	System	23 Jan 2021 14:36:18
User opened query 'Data is required. Please complete.' (Site from System).	Laila Hussaini (b) (4)	23 Jan 2021 14:36:18
User entered empty.	(b) (4)	
	System	21 Jan 2021 15:38:06
	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 08:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:08:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User accepted default value 'Day 9 (Day 9)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:08:32

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
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	23 Jan 2021 14:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	System	23 Jan 2021 14:36:18
User opened query 'Data is required. Please complete.' (Site from System).	Laila Hussaini (b) (4)	23 Jan 2021 14:36:18
User entered empty.	(b) (4)	
	System	21 Jan 2021 15:38:06
	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 08:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:08:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User accepted default value 'Day 14 (Day 14)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:38:06

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:08:32

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Jan 2021 14:36:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Jan 2021 14:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	23 Jan 2021 14:36:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 15:38:06
User entered empty.	System	21 Jan 2021 15:38:06
	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06
	(b) (4)	

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 08:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:08:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User accepted default value 'Day 21 (Day 21)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:08:32

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Jan 2021 14:36:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Jan 2021 14:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	23 Jan 2021 14:36:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 15:38:06
User entered empty.	System	21 Jan 2021 15:38:06
	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06
	(b) (4)	

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 08:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:08:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User accepted default value 'Day 28 (Day 28)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:08:32

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Jan 2021 14:36:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Jan 2021 14:36:18
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Laila Hussaini (b) (4)	23 Jan 2021 14:36:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 15:38:06
User entered empty.	System	21 Jan 2021 15:38:06
	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06
	(b) (4)	

US3532276

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 08:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:38:06

US3532276

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:08

US3532276

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '19 Jan 2021'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:08

US3532276

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[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 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Clinic (Clinic)'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:08

US3532276

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User entered 'SICKD1'	System	20 Jan 2021 11:34:08

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '19 Jan 2021'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '15:10'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User entered '19 Jan 2021 15:10'	System	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:34:51
DataPoint set to visible.	(b) (4) System	20 Jan 2021 11:34:08

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered missing code ND - Not Done.	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:34:51
DataPoint set to visible.	(b) (4) System	20 Jan 2021 11:34:08

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '97.1' F	Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Oral (Oral)'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '77'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User entered 'bpm'	System	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '22'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User entered 'breaths/min'	System	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 05:41:30
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' answered with 'NCS' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	02 Feb 2021 20:04:45
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:32:43
User entered '166'	Laila Hussaini (b) (4) (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User entered 'mmHg'	System	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '88'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User entered 'mmHg'	System	20 Jan 2021 11:34:51

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25

US3532276

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25

US3532276

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:59

US3532276

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '19 Jan 2021'	Laila Hussaini (b) (4)	20 Jan 2021 11:34:59

US3532276

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:08:32

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	(b) (4) Laila Hussaini (b) (4)	20 Jan 2021 11:35:09

US3532276

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 08:08:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:35:25
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 19 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 18:19:47
Query 'Per Lab Recon: SARS-COV2: Sample dated 19 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'Shipped on 1/20/2021' (Site from DM).	Laila Hussaini (b) (4) (b) (4)	02 Feb 2021 20:03:42
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 19 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 12:26:37
User entered '19 Jan 2021'	Laila Hussaini (b) (4) (b) (4)	20 Jan 2021 11:35:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:13:10

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '6 Jan 2021'	Lisa Macoy (b) (4)	06 Jan 2021 17:13:10

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	06 Jan 2021 17:13:10

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 17:13:10

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '6 Jan 2021'	Lisa Macoy (b) (4)	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:45:47

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:45:47

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '6 Jan 2021'	Lisa Macoy (b) (4)	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Placebo (Placebo)'	Lisa Macoy (b) (4)	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 04:31:42
User entered 'Placebo (Placebo)'	Lisa Macoy (b) (4)	06 Jan 2021 17:14:30
	(b) (4)	

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 04:31:42
User entered 'Placebo (Placebo)'	Lisa Macoy (b) (4)	06 Jan 2021 17:14:30
	(b) (4)	

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '1'	System	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:08:32

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'I'	System	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered empty.	System	06 Jan 2021 17:33:38
DataPoint set to visible.	System	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered empty.	System	06 Jan 2021 17:33:38
DataPoint set to visible.	System	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Macoy (b) (4) (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '6 Jan 2021'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '10:55'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '6 Jan 2021 10:55'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '97.4' F	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '74'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'bpm'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '20'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'breaths/min'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '149'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '88'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered missing code ND - Not Done.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:08:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered empty.	System	06 Jan 2021 17:33:38
DataPoint set to visible.	System	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '6 Jan 2021'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '12:17'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '6 Jan 2021 12:17'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '97' F	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '69'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'bpm'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '20'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'breaths/min'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '132'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '83'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	06 Jan 2021 17:33:38

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'No (N)'	Lisa Macoy (b) (4)	06 Jan 2021 17:33:46

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	06 Jan 2021 17:33:46

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mRNA-1273'	System	06 Jan 2021 17:23:09
DataPoint set to visible.	System	06 Jan 2021 17:14:30

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '6 Jan 2021'	Lisa Macoy (b) (4)	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '11:44'	Lisa Macoy (b) (4)	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '6 Jan 2021 11:44'	System	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Left Arm (LEFT ARM)'	Lisa Macoy (b) (4)	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'ONCE'	System	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 17:23:09

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:25:24

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '6 Jan 2021'	Lisa Macoy (b) (4)	06 Jan 2021 17:25:24

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '11:11'	Lisa Macoy (b) (4)	06 Jan 2021 17:25:24

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '6 Jan 2021 11:11'	System	06 Jan 2021 17:25:24

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:28:11

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '6 Jan 2021'	Lisa Macoy (b) (4)	06 Jan 2021 17:28:11

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '11:01'	Lisa Macoy (b) (4)	06 Jan 2021 17:28:11

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:08:32

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '6 Jan 2021 11:01'	System	06 Jan 2021 17:28:11

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	06 Jan 2021 17:28:18

US3532276

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'I'	System	06 Jan 2021 17:28:18

US3532276

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	14 Jan 2021 21:19:32

US3532276

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '14 Jan 2021'	Lisa Macoy (b) (4)	14 Jan 2021 21:19:32

US3532276

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	14 Jan 2021 21:19:32

US3532276

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	14 Jan 2021 21:19:32

US3532276

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	14 Jan 2021 21:19:39

US3532276

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'I'	System	14 Jan 2021 21:19:39

US3532276

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '1'	System	14 Jan 2021 21:19:39
DataPoint set to visible.	System	14 Jan 2021 21:19:39

US3532276

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 16:17:33

US3532276

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '3 Feb 2021'	Lisa Macoy (b) (4)	03 Feb 2021 16:17:33

US3532276

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	03 Feb 2021 16:17:33

US3532276

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'OLD29'	System	03 Feb 2021 16:17:33

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User accepted default value 'Pre-Dose (PREDOSE)'	Lisa Macoy (b) (4) (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '3 Feb 2021'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '10:34'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '3 Feb 2021 10:34'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '97.7' F	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '93'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'bpm'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '20'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'breaths/min'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '137'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '83'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User accepted default value 'Post-Dose (POSTDOSE)'	Lisa Macoy (b) (4) (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '3 Feb 2021'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '12:17'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '3 Feb 2021 12:17'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '97.6' F	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '82'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'bpm'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '20'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'breaths/min'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '136'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '81'	Lisa Macoy (b) (4)	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:08:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	03 Feb 2021 17:36:51

US3532276

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 16:17:45

US3532276

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '3 Feb 2021'	Lisa Macoy (b) (4)	03 Feb 2021 16:17:45

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mRNA-1273'	System	03 Feb 2021 17:34:09
DataPoint set to visible.	System	14 Jan 2021 21:19:39

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '3 Feb 2021'	Lisa Macoy (b) (4)	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '11:45'	Lisa Macoy (b) (4)	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '3 Feb 2021 11:45'	System	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Left Arm (LEFT ARM)'	Lisa Macoy (b) (4)	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'ONCE'	System	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:08:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 17:34:09

US3532276

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 17:33:14

US3532276

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'I'	System	03 Feb 2021 17:33:14

US3532276

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Feb 2021 19:22:24

US3532276

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered '10 Feb 2021'	Lisa Macoy (b) (4)	10 Feb 2021 19:22:24

US3532276

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Contact Made (CONTACT MADE)'	Lisa Macoy (b) (4)	10 Feb 2021 19:22:24

US3532276

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:08:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered empty.	Lisa Macoy (b) (4)	10 Feb 2021 19:22:24

US3532276

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	10 Feb 2021 19:22:31

US3532276

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:08:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'I'	System	10 Feb 2021 19:22:31

US3532276

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	04 Mar 2021 15:27:32

US3532276

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '4 Mar 2021'	Lisa Macoy (b) (4)	04 Mar 2021 15:27:32

US3532276

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Clinic (Clinic)'	Lisa Macoy (b) (4)	04 Mar 2021 15:27:32

US3532276

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:08:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'OLD57'	System	04 Mar 2021 15:27:32

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '4 Mar 2021'	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '09:53'	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '4 Mar 2021 09:53'	System	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '97.4' F	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Oral (Oral)'	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '72'	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'bpm'	System	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '18'	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'breaths/min'	System	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '138'	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '76'	Lisa Macoy (b) (4)	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered 'mmHg'	System	04 Mar 2021 15:28:22

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46

US3532276

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:08:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46

US3532276

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'No (N)'	Lisa Macoy (b) (4)	04 Mar 2021 15:33:30

US3532276

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:08:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:33:30

US3532276

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	04 Mar 2021 15:35:03

US3532276

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is recorded under Participant Decision/OL-D57 visit in EDC, however the same is reported under OL-3 Visit with date 08MAR2021 in PPD Central lab. Please review and confirm the CORRECT DATE in query response for this Visit. Else Clarify, Thank you ' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is recorded under Participant Decision/OL-D57 visit in EDC, however the same is reported under OL-3 Visit with date 08MAR2021 in PPD Central lab. Please review and confirm the CORRECT DATE in query response for this Visit. Else Clarify, Thank you ' answered with 'CORRECT DATE' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 07:11:17
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 04MAR2021 is recorded under Participant Decision/OL-D57 visit in EDC, however the same is reported under OL-3 Visit with date 08MAR2021 in PPD Central lab. Please review and confirm the CORRECT DATE in query response for this Visit. Else Clarify, Thank you ' (Site from DM).	Laila Hussaini (b) (4)	25 Mar 2021 13:54:47
User entered '4 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 12:02:11
	Lisa Macoy (b) (4)	04 Mar 2021 15:35:03

US3532276

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered '10:00'	Lisa Macoy (b) (4)	04 Mar 2021 15:35:03

US3532276

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:08:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:31:46
User entered '4 Mar 2021 10:00'	System	04 Mar 2021 15:35:03

US3532276

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:08:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:42:30
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:45:01
User signature succeeded.	Evan Anderson (b) (4)	19 Mar 2021 09:18:29
User entered 'Yes (Y)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	08 Oct 2020 14:23:05

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 21:12:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 21:12:29
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 14:26:44
User entered 'chills'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '3 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User entered empty.	System	08 Oct 2020 14:26:35

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '4 Oct 2020'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User entered empty.	System	08 Oct 2020 14:26:35

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(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)	29 Apr 2021 00:07:59
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'None (NONE)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'I'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(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)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	08 Oct 2020 14:26:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User entered '0'	System	08 Oct 2020 14:26:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59
User entered '0'	System	08 Oct 2020 14:26:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:07:59

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'For coding purposes, REPAIR OF CROWN ON TOOTH is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4) (b) (4), (b) (6)	14 Mar 2021 20:39:51
User closed query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:00:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth fracture, LLT: Tooth fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Jan 2021 14:10:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Jan 2021 14:10:42
Data point term sent to Coder	System	08 Jan 2021 19:59:30
Query 'For coding purposes, REPAIR OF CROWN ON TOOTH is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'updated' (Site from Coder).	Lisa Macoy (b) (4) (b) (4)	08 Jan 2021 19:59:19
Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	08 Jan 2021 19:59:11
Coding entries removed.	Lisa Macoy (b) (4) (b) (4)	08 Jan 2021 19:58:52
User entered 'Broken CROWN ON TOOTH' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	08 Jan 2021 19:58:52

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, REPAIR OF CROWN ON TOOTH is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6)	08 Jan 2021 17:26:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Tooth disorder, LLT: Tooth disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:40:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:40:40
User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:22:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Tooth repair, LLT: Tooth repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:20:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:20:33
Data point term sent to Coder	System	09 Nov 2020 12:52:04
User entered 'repair of crown on tooth'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 12:51:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '28 Oct 2020'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User entered empty.	System	09 Nov 2020 12:51:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '28 Oct 2020'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User entered empty.	System	09 Nov 2020 12:51:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 12:51:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 12:51:59
User entered 'None (NONE)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	09 Nov 2020 12:51:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 12:51:48
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 04:35:47
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4)	11 Jan 2021 13:24:36
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Lisa Macoy (b) (4)	11 Jan 2021 13:24:31
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:22:24
User entered '1'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'I'	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 12:52:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 12:52:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lisa Macoy (b) (4)	09 Nov 2020 12:52:12
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 12:51:48
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:51:48
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User entered '0'	System	09 Nov 2020 12:51:48

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03
User entered '1'	System	09 Nov 2020 12:51:48

US3532276

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:03

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eyes aggravated - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 11:47:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 11:47:31
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 12:54:04
User entered 'worsening left dry eye'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '01 Nov 2020'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User entered empty.	System	09 Nov 2020 12:53:57

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	03 Dec 2020 15:35:50
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '23 Nov 2020' reason for change: Data Entry Error	Lisa Macoy (b) (4)	03 Dec 2020 15:35:50
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User entered empty.	System	09 Nov 2020 12:53:57

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'None (NONE)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of DRY LEFT EYE. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 08:12:25
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of DRY LEFT EYE. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' answered with 'no new medications' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	11 Jan 2021 13:29:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of DRY LEFT EYE. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:22:37
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	09 Nov 2020 12:53:57

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lisa Macoy (b) (4)	03 Dec 2020 15:35:50
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'worsening dry eyes, using eye drops. subject to follow with opth'	Lisa Macoy (b) (4)	09 Nov 2020 12:53:57
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User entered '0'	System	09 Nov 2020 12:53:57

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07
User entered '0'	System	09 Nov 2020 12:53:57

US3532276

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:07

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Rhinitis allergic - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Nov 2020 00:30:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 00:30:44
Data point term sent to Coder	System	10 Nov 2020 19:44:32
User entered 'Rhinitis- allergic'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 19:43:58

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '20 Oct 2020'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:43:58

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 07:29:18
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'continuing, subject states even continues all winter due to allergy season' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	11 Jan 2021 13:30:39
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:22:49
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 19:43:58

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	10 Nov 2020 19:44:32
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 19:44:32
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 19:43:58
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:43:58

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'None (NONE)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

None

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:26:41
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'no new medication. Stated PRN medication listed in conmeds' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	11 Jan 2021 13:32:06
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Dec 2020 03:22:57
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 19:43:58

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Lisa Macoy (b) (4)	10 Nov 2020 19:44:32
Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	10 Nov 2020 19:43:58
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'runny nose- clear, started after cleaning out attic, hx of seasonal allergies'	(b) (4) Lisa Macoy (b) (4) (b) (4)	10 Nov 2020 19:43:58

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 19:43:58

US3532276

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 19:43:58

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 10:42:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 10:42:26
	(b) (4)	
User closed query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.	(b) (4), (b) (6)	30 Mar 2021 08:41:21
' (Site from DM).		
Data point term sent to Coder	System	29 Mar 2021 17:03:21
Query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.	Lisa Macoy (b) (4)	29 Mar 2021 17:03:03
	(b) (4)	
' answered with 'updated' (Site from DM).		
Coding entries removed.	Lisa Macoy (b) (4)	29 Mar 2021 17:02:45
	(b) (4)	
User entered 'UPPER RESPIRATORY INFECTION- etiology unknown' reason for change: New Information	Lisa Macoy (b) (4)	29 Mar 2021 17:02:45
	(b) (4)	
User opened query 'Per MM: Please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.	(b) (4), (b) (6)	18 Mar 2021 15:53:19
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 16:15:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 16:15:26
	(b) (4)	
Data point term sent to Coder	System	03 Feb 2021 16:15:08
User entered 'upper respiratory infection'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '11 Jan 2021'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User entered empty.	System	03 Feb 2021 16:15:00

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '3 Feb 2021'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User entered empty.	System	03 Feb 2021 16:15:00

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 16:15:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 16:15:19
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	03 Feb 2021 16:15:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 16:15:00
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'None (NONE)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'I'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	03 Feb 2021 16:15:00
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User entered '0'	System	03 Feb 2021 16:15:19

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13
User entered '1'	System	03 Feb 2021 16:15:00

US3532276

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 00:08:13

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:45:21
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:20:47
User entered		
'USA-US077-2021-mRNA-1273-P301000002'	System	11 Feb 2021 14:20:41
User entered 'New'	(b) (4), (b) (6)	11 Feb 2021 14:20:41

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Exacerbation of asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 20:04:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 20:04:56
Data point term sent to Coder	System	10 Feb 2021 20:03:49
User entered 'asthma exacerbation'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '4 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'please check if Time is supported by source' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:53:55
User opened query 'please check if Time is supported by source' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:36:01
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Feb 2021 20:04:04
User entered '08:00' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Feb 2021 20:02:49
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Feb 2021 08:00'	System	10 Feb 2021 20:04:04
User entered empty.	System	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '10 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Query 'please check if Time is supported by source' canceled (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 20:53:57
User opened query 'please check if Time is supported by source' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:36:27
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '08:00' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:05:30
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Feb 2021 20:04:04
User entered '15:00' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:04:04
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Feb 2021 20:02:49
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Feb 2021 08:00'	System	10 Feb 2021 20:05:30
User entered '10 Feb 2021 15:00'	System	10 Feb 2021 20:04:04
User entered empty.	System	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'Grade 4 (Grade 4)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Feb 2021 20:04:04
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	10 Feb 2021 20:02:49
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	10 Feb 2021 20:04:04
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	10 Feb 2021 20:04:04
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	10 Feb 2021 20:04:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	10 Feb 2021 20:02:49
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '8 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '9 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'Not Applicable (NOT APPLICABLE)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

None

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '0'	Lisa Macoy (b) (4)	10 Feb 2021 20:02:49
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:45:21
User entered 'not related to vaccine, due to underlying asthma exacerbation. Admitted to observation unit only for less than 24hrs, Uncertain if need to be an SAE, but will report for now.'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 20:02:49

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Exacerbation of asthma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Mar 2021 15:45:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Mar 2021 15:45:52
Data point term sent to Coder	System	05 Mar 2021 15:44:47
User entered 'Asthma Exacerbation'	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 15:43:55

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '27 Feb 2021'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 15:43:55

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 16:27:16
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	03 May 2021 15:41:34
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	03 May 2021 15:41:34
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 16:27:16
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	03 May 2021 15:41:34
	(b) (4)	
User entered '15 Apr 2021' reason for change: New Information	Lisa Macoy (b) (4)	03 May 2021 15:41:34
	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 15:43:55

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 17:08:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 17:08:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lisa Macoy (b) (4)	29 Mar 2021 17:08:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 15:43:55
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	03 Apr 2021 03:59:59
User entered 'I'	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 15:43:55

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	03 Apr 2021 03:59:59
User entered '0'	Lisa Macoy (b) (4) (b) (4)	05 Mar 2021 15:43:55

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 May 2021 16:27:16
	(b) (4)	
Signature has been broken.	Lisa Macoy (b) (4)	03 May 2021 15:41:34
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lisa Macoy (b) (4)	03 May 2021 15:41:34
New Information	(b) (4)	
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Mar 2021 15:43:55
	(b) (4)	

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Mar 2021 15:43:55

US3532276

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:08:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 15:43:55

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:08:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:42:30
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:29:09

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:31:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:31:49
Data point term sent to Coder	System	10 Sep 2020 17:30:43
User entered 'biotin'	(b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'General Health'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '5000'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:30:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:38:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:38:49
Data point term sent to Coder	System	10 Sep 2020 17:38:01
User entered 'Flonase'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Seasonal Allergies'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '44' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	30 Oct 2020 15:25:25
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	18 Sep 2020 12:18:38
	(b) (4)	
User entered 'unk'	(b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'ug (ug)' reason for change: Per Query Resolution	Lisa Macoy (b) (4)	30 Oct 2020 15:25:25
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 07:02:24
Query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 15:25:31
User entered empty; reason for change Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 15:25:25
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:13:52
Query 'Per CDM CR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:13:41
User opened query 'Per CDM CR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 07:47:55
User entered 'spray' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	18 Sep 2020 12:18:38
User entered 'unknown'	(b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:37:08

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: METHYLCELLULOSE, PRODUCTSYNONYM: CITRUCEL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 09:25:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 09:25:45
Data point term sent to Coder Coding entries removed.	System Lisa Macoy (b) (4)	18 Sep 2020 12:20:57 18 Sep 2020 12:20:45
User entered 'CITRUCEL' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	18 Sep 2020 12:20:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: METHYLCELLULOSE, PRODUCTSYNONYM: CITRUCEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 12:46:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 12:46:48
Data point term sent to Coder User entered 'Citrucal'	System (b) (4), (b) (6)	10 Sep 2020 17:39:04 10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'General Health'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Lisa Macoy (b) (4)	18 Sep 2020 12:19:16
	(b) (4)	
User entered 'unk'	(b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'tablet (TABLET)' reason for change:	Lisa Macoy (b) (4)	18 Sep 2020 12:19:16
Data Entry Error	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty; reason for change Data Entry Error	Lisa Macoy (b) (4)	18 Sep 2020 12:19:16
	(b) (4)	
User entered 'unknown'	(b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:38:31

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL HFA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:41:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:41:39
Data point term sent to Coder	System	10 Sep 2020 17:41:06
User entered 'Albuterol HFA'	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Mild intermediate Asthma'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '90'	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:40:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:43:46
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Sep 2020 17:43:46
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	10 Sep 2020 17:43:16
User entered 'Atorvastatin'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered 'High Cholesterol'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered '10'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered 'un Nov 2019'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:06:48
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:42:29

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:42:29

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:08:32
[Name of Medication](#)

PRODUCTION RELEASE (v12.003
EAB) (1725) 2886 of 3358

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '75'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:43:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:18
Data point term sent to Coder	System	10 Sep 2020 17:45:26
User entered 'Celecoxib'	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Osteoarthritis'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '100'	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:44:45

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTROGENS CONJUGATED, PRODUCTSYNONYM: PREMARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:47:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 17:47:37
Data point term sent to Coder	System	10 Sep 2020 17:46:29
User entered 'Premarin'	(b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Hysterectomy'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0.3'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 1985'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'please check if Stop Date should be updated (after Pt's hospitalization in Feb 2021)' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:37:29
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
Query 'please check if Stop Date should be updated (after Pt's hospitalization in Feb 2021)' answered with 'spoke to subject- still taking' (Site from CRA).	Lisa Macoy (b) (4)	07 Apr 2021 13:39:14
User opened query 'please check if Stop Date should be updated (after Pt's hospitalization in Feb 2021)' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 18:26:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:46:01

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Sep 2020 00:17:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 00:17:44
Data point term sent to Coder	System	10 Sep 2020 17:50:39
User entered 'Ketaconazole'	(b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Candid dermatitis'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'application'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:50:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 17:53:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:53:48
Data point term sent to Coder	System	10 Sep 2020 17:52:42
User entered 'Probiotic'	(b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'General Health'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:52:07

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:09:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:54:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:54:42
Data point term sent to Coder	System	10 Sep 2020 17:53:45
User entered 'Levothyroxine'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered 'Hypothyroidism'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered '50'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered 'ug (ug)'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 17:53:34
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:09:38
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:53:10

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User closed query 'please check if Stop Date should be updated (after Pt's hospitalization in Feb 2021)' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 21:37:01
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
Query 'please check if Stop Date should be updated (after Pt's hospitalization in Feb 2021)' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4)	07 Apr 2021 13:40:43
User opened query 'please check if Stop Date should be updated (after Pt's hospitalization in Feb 2021)' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 18:25:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 07:52:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 07:52:49
Data point term sent to Coder	System	10 Sep 2020 17:55:48
User entered 'Meloxicam'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Right knee total replacement'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '15'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'un UNK 2019'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4)	07 Apr 2021 13:40:36
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'un UNK 2020' reason for change: New Information	Lisa Macoy (b) (4)	07 Apr 2021 13:40:36
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User entered empty.	System	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User entered empty.	System	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:44:42
User entered empty.	System	10 Sep 2020 17:54:47

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:56:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:56:47
Data point term sent to Coder	System	10 Sep 2020 17:55:48
User entered 'Omeprazole'	(b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '20'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:55:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:55:37

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:08:32
[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 17:57:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 17:57:51
Data point term sent to Coder	System	10 Sep 2020 17:56:51
User entered 'B12'	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'General Health'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '1000'	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:56:16

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:58:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:58:45
Data point term sent to Coder	System	10 Sep 2020 17:57:56
User entered 'Vitamin D3'	(b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'General Health'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '50'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 17:56:59

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 20:56:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 20:56:16
Data point term sent to Coder	System	15 Oct 2020 19:36:03
User entered 'amoxicillin'	Lisa Macoy (b) (4) (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User closed query 'Per DM CLR: Please review if this procedure should be recorded in Concomitant Procedure ecrf and if there is an associated condition related to this procedure, please record event in AE ecrf. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 07:30:30
Query 'Per DM CLR: Please review if this procedure should be recorded in Concomitant Procedure ecrf and if there is an associated condition related to this procedure, please record event in AE ecrf. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	10 Dec 2020 19:47:27
User opened query 'Per DM CLR: Please review if this procedure should be recorded in Concomitant Procedure ecrf and if there is an associated condition related to this procedure, please record event in AE ecrf. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 20:23:30
User entered 'dental procedures'	Lisa Macoy (b) (4) (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'I'	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'g (g)'	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)' reason for change:	(b) (4)	
New Information	Lisa Macoy (b) (4)	11 Dec 2020 12:24:14
User entered 'as needed (PRN)'	(b) (4)	
	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '14 Oct 2020'	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Lisa Macoy (b) (4)	15 Oct 2020 19:37:32
User entered 'Yes (Y)'	(b) (4)	
	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '15 Oct 2020' reason for change: New Information	(b) (4) Lisa Macoy (b) (4)	11 Dec 2020 12:24:14
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	15 Oct 2020 19:37:32
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	15 Oct 2020 19:35:40
User entered '14 Oct 2020'	Lisa Macoy (b) (4) (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	Lisa Macoy (b) (4)	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User entered '1'	System	11 Dec 2020 12:24:14
User entered empty.	System	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User entered '1'	System	11 Dec 2020 12:24:14
User entered empty.	System	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:37:55
User entered '804 (804)'	System	11 Dec 2020 12:24:14
User entered empty.	System	15 Oct 2020 19:35:40

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 15:15:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 15:15:07
Data point term sent to Coder	System	11 Jan 2021 13:27:09
Coding entries removed.	Lisa Macoy (b) (4)	11 Jan 2021 13:26:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 17:26:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 17:26:10
Data point term sent to Coder	System	30 Oct 2020 16:49:43
User entered 'Amoxicillin'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User closed query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for DENTAL PROCEDURES). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 04:36:49
Query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for DENTAL PROCEDURES). Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	11 Jan 2021 13:26:17
User entered 'Prophylaxis for DENTAL PROCEDURES' reason for change: Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	11 Jan 2021 13:26:12
User opened query 'Per DM CLR: Please update the indication of this medication to include the term Prophylaxis and the medical condition being prevented (e.g. prophylaxis for DENTAL PROCEDURES). Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:22:00
User entered 'dental procedures'	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'I'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'g (g)'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once (ONCE)'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '28 Oct 2020'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '28 Oct 2020'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User entered empty.	System	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User entered empty.	System	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:02
User entered empty.	System	30 Oct 2020 16:49:26

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: MACROGOL 400;PROPYLENE GLYCOL, PRODUCTSYNONYM: SYSTANE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Jan 2021 16:51:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 16:51:02
Data point term sent to Coder Coding entries removed.	System Lisa Macoy (b) (4) (b) (4)	11 Jan 2021 13:28:10 11 Jan 2021 13:27:40
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: MACROGOL 400;PROPYLENE GLYCOL, PRODUCTSYNONYM: SYSTANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:41:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:41:29
Data point term sent to Coder User entered 'Systane eye drops [Polyethylene Glycol 400 and Propylene Glycol]'	System Lisa Macoy (b) (4) (b) (4)	05 Nov 2020 19:13:14 05 Nov 2020 19:12:25

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'dry eye left'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '1'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Other (OTHER)'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'drop'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'as needed (PRN)'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 05:54:01
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	11 Jan 2021 13:27:46
User entered 'Other (OTHER)' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	11 Jan 2021 13:27:40
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:22:57
User entered 'Intraocular (INTRAOCULAR)'	Lisa Macoy (b) (4) (b) (4)	05 Nov 2020 19:12:25

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Ophthalmic' reason for change: Data Entry Error	Lisa Macoy (b) (4)	11 Jan 2021 13:28:09
	(b) (4)	
User entered 'ocular' reason for change: Data Entry Error	Lisa Macoy (b) (4)	11 Jan 2021 13:27:40
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'un UNK 2015'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	05 Nov 2020 19:12:25
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:12:25

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:12:25

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:12:25

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
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)	14 Dec 2020 17:53:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 17:53:01
Data point term sent to Coder	System	03 Dec 2020 15:36:00
User entered 'Influenza vaccine'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'influenza'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0.5'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mL (mL)'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once (ONCE)'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Intramuscular (INTRAMUSCULAR)'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '17 Nov 2020'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '17 Nov 2020'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	Lisa Macoy (b) (4)	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User entered empty.	System	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User entered empty.	System	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:13
User entered empty.	System	03 Dec 2020 15:35:05

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Jan 2021 15:43:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 15:43:02
Data point term sent to Coder	System	21 Jan 2021 15:42:14
User entered 'Zinc'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:41:30

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'general health'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '50'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'mg (mg)'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'once daily (QD)'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Oral (ORAL)'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '24 Dec 2020'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '0'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	Laila Hussaini (b) (4)	21 Jan 2021 15:41:30
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 15:41:30

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 15:41:30

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 15:41:30

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 15:54:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 15:54:16
Data point term sent to Coder	System	21 Jan 2021 15:42:13
User entered 'Prednisone'	Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'AE #5'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '20'	(b) (4) Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mg (mg)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'once daily (QD)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '20 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4) Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
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)	08 Apr 2021 14:50:22
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).	Lisa Macoy (b) (4) (b) (4)	07 Apr 2021 13:41:57
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4) (b) (4)	07 Apr 2021 13:41:51
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)	05 Apr 2021 09:48:43
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '26 Jan 2021' reason for change: New Information	Lisa Macoy (b) (4)	07 Apr 2021 13:41:51
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User entered '1'	System	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User entered '1'	System	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:25
User entered '804 (804)'	System	21 Jan 2021 15:42:03

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: CODEINE;GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 15:53:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 15:53:03
Data point term sent to Coder	System	21 Jan 2021 15:43:15
User entered 'Codeine-Guaifen'	Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'AE #5'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '10-100'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mL (mL)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'as needed (PRN)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '20 Jan 2021'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
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)	08 Apr 2021 14:50:30
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).	Lisa Macoy (b) (4) (b) (4)	07 Apr 2021 13:43:08
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4) (b) (4)	07 Apr 2021 13:43:03
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)	05 Apr 2021 09:48:51
User entered 'Yes (Y)'	Laila Hussaini (b) (4) (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '23 Jan 2021' reason for change: New Information	Lisa Macoy (b) (4)	07 Apr 2021 13:43:03
User entered empty.	Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	(b) (4) Laila Hussaini (b) (4)	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User entered empty.	System	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User entered empty.	System	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:38:35
User entered empty.	System	21 Jan 2021 15:42:42

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:01:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:01:46
Data point term sent to Coder	System	10 Feb 2021 20:27:42
User entered 'solumedrol'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered 'Asthma exacerbation'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered '125'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered 'mg (mg)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered 'once (ONCE)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered 'Intravenous (INTRAVENOUS)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered empty.	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered '8 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered '0'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered '8 Feb 2021'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:32:16
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User entered empty.	System	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User entered empty.	System	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:00
User entered empty.	System	10 Feb 2021 20:27:27

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User closed query 'please check with source if Prednisolone (50 mg) since 08Feb21 was administered to Pt' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Evan Anderson (b) (4)	15 Apr 2021 21:38:40 09 Apr 2021 08:28:31
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:16:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 16:16:54
Query 'please check with source if Prednisolone (50 mg) since 08Feb21 was administered to Pt' answered with 'verified' (Site from CRA).	Lisa Macoy (b) (4) (b) (4)	07 Apr 2021 13:44:16
Data point term sent to Coder Coding entries removed.	System Lisa Macoy (b) (4) (b) (4)	06 Apr 2021 17:44:47 06 Apr 2021 17:43:54
User opened query 'please check with source if Prednisolone (50 mg) since 08Feb21 was administered to Pt' (Site from CRA). User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	30 Mar 2021 18:44:01 17 Feb 2021 12:01:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:01:58
Data point term sent to Coder User entered 'methylprednisolone'	System Lisa Macoy (b) (4) (b) (4)	12 Feb 2021 18:41:58 12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication within the timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:50:41
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication within the timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Lisa Macoy (b) (4) (b) (4)	06 Apr 2021 17:44:03
User entered 'Mild Intermittent ASTHMA EXACERBATION' reason for change: Per Query Resolution	Lisa Macoy (b) (4) (b) (4)	06 Apr 2021 17:43:54
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication within the timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:24:34
User entered 'asthma exacerbation'	Lisa Macoy (b) (4) (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '4'	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'mg (mg)'	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'unknown (UNKNOWN)'	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered empty.	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '10 Feb 2021' reason for change: New Information	Lisa Macoy (b) (4)	29 Mar 2021 18:26:49
User entered '9 Feb 2021'	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '0'	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
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 09:22:38
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).	Lisa Macoy (b) (4) (b) (4)	29 Mar 2021 18:26:53
User entered 'No (N)' reason for change: New Information	Lisa Macoy (b) (4) (b) (4)	29 Mar 2021 18:26:49
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)	10 Mar 2021 10:35:46
User entered 'Yes (Y)'	Lisa Macoy (b) (4) (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered '16 Feb 2021' reason for change: New Information	Lisa Macoy (b) (4)	29 Mar 2021 18:26:49
User entered empty.	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'No (N)'	Lisa Macoy (b) (4)	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User entered empty.	System	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User entered empty.	System	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:10
User entered empty.	System	12 Feb 2021 18:41:57

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Mar 2021 15:31:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 15:31:07
Data point term sent to Coder	System	04 Mar 2021 15:30:54
User entered 'Singulair'	Lisa Macoy (b) (4) (b) (4)	04 Mar 2021 15:29:54

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
User entered 'Asthma exacerbation'	(b) (4) Lisa Macoy (b) (4) (b) (4)	04 Mar 2021 15:29:54

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '10'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'mg (mg)'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'once daily (QD)'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Oral (ORAL)'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	04 Mar 2021 15:33:20
User entered '02 Mar 2021' reason for change: Data Entry Error	Lisa Macoy (b) (4)	04 Mar 2021 15:33:20
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	04 Mar 2021 15:29:54
User entered '09 Mar 2021'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered '0'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
	(b) (4)	
User entered 'No (N)'	Lisa Macoy (b) (4)	04 Mar 2021 15:29:54
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 15:29:54

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 15:29:54

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 15:29:54

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALMETEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 11:53:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 11:53:49
	(b) (4)	
Data point term sent to Coder	System	04 Mar 2021 15:38:05
User entered 'Fluticasone Propionate Salmeterol Diskus'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered 'No (N)'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered 'Asthma Exacerbation'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered 'unk'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered 'ug (ug)'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered 'twice daily (BID)'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered '02 Mar 2021'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered '0'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered empty.	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	09 Apr 2021 08:28:31
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:35:18
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:34:49
DataPoint Un-verified.	(b) (4), (b) (6)	30 Mar 2021 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:19:43
User entered 'No (N)'	Lisa Macoy (b) (4)	04 Mar 2021 15:37:37
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Mar 2021 15:37:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 15:37:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 15:37:37

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 15:08:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:08:02
Data point term sent to Coder	System	16 Apr 2021 15:06:45
User entered 'prednisone'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'Asthma exacerbation'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '50'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'mg (mg)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'once (ONCE)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 15:05:53
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'Oral (ORAL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '09 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '09 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:55:41
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
User entered empty.	System	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
User entered empty.	System	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:19
User entered empty.	System	16 Apr 2021 15:05:53

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:51:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:51:52
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	16 Apr 2021 16:09:26
Data point term sent to Coder	System	16 Apr 2021 15:36:19
User entered 'sodium chloride'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'asthma exacerbation'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '1000'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'mL (mL)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered empty.	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'once (ONCE)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 15:36:15
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered empty.	(b) (4)	
	Lisa Macoy (b) (4)	16 Apr 2021 15:36:15
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '08 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '0'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered '08 Feb 2021'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:47
User signature succeeded.	Evan Anderson (b) (4)	16 Apr 2021 16:09:26
User entered 'No (N)'	(b) (4) Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
User entered empty.	System	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
User entered empty.	System	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:28
User entered empty.	System	16 Apr 2021 15:36:15

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:48:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:48:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:11
Data point term sent to Coder	System	16 Apr 2021 16:26:32
User entered 'Albuterol CFC'	Lisa Macoy (b) (4)	16 Apr 2021 16:25:39
	(b) (4)	

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered 'asthma exacerbation'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered '180'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered 'ug (ug)'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered 'as needed (PRN)'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered empty.	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 02:24:00
User closed query 'please change the year to 2021' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 02:23:36
Query 'please change the year to 2021' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 21:59:34
User entered '09 Feb 2021' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 21:59:09
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:28
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:11
User opened query 'please change the year to 2021' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:52:23
User entered '09 Feb 2020'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered '0'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 02:24:12
User closed query 'please change the year to 2021' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 02:23:49
Query 'please change the year to 2021' answered with 'updated' (Site from CRA).	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 21:59:50
User entered '09 Feb 2021' reason for change: Data Entry Error	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 21:59:09
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:30
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:54:11
User opened query 'please change the year to 2021' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:52:22
User entered '09 Feb 2020'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User signature succeeded.	Evan Anderson (b) (4)	20 Apr 2021 15:50:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:54:11
User entered 'No (N)'	Lisa Macoy (b) (4) (b) (4)	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User entered empty.	System	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User entered empty.	System	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:08:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:39:35
User entered empty.	System	16 Apr 2021 16:25:39

US3532276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:08:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:42:30
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
User entered 'Yes (Y)'	Lisa Macoy (b) (4)	30 Oct 2020 16:49:35

US3532276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:08:32

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered '28 Oct 2020'	Lisa Macoy (b) (4)	30 Oct 2020 16:50:04
	(b) (4)	

US3532276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:08:32

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'broken crown on tooth repaired'	Lisa Macoy (b) (4)	30 Oct 2020 16:50:04
	(b) (4)	

US3532276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:08:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 03:59:59
	(b) (4)	
User entered 'Adverse Event (AE)'	Lisa Macoy (b) (4)	30 Oct 2020 16:50:04
	(b) (4)	

US3532276

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:08:32

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4) (b) (4)	03 Apr 2021 03:59:59
User entered empty.	Lisa Macoy (b) (4) (b) (4)	30 Oct 2020 16:50:04

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered		
'USA-US077-2021-MRNA-1273-P301000002'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Yes (Y)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:52:33
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:52:26
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:52:20
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'sent 02/23/2021' (Site from Safety).	Lisa Macoy (b) (4) (b) (4)	23 Feb 2021 16:43:48
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'Overnight hours for observation of less than 24hrs. Please clarify if SAE is needed.' (Site from Safety).	Lisa Macoy (b) (4) (b) (4)	23 Feb 2021 16:43:36

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'PCR - NP negative. Report sent 02/23/2021' (Site from Safety).	Lisa Macoy (b) (4) (b) (4)	23 Feb 2021 16:40:32
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:52:05
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:48:49
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:48:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Yes (Y)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Evan'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Anderson'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered '2015 Uppergate Drive'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Atlanta'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'GA'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered '30323'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
User entered 'US'	System	11 Feb 2021 14:21:09

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Feb 2021 14:21:09

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'USA-US077-2021-MRNA-1273-P301000002'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Yes (Y)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:52:33
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:52:26
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:52:20
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'sent 02/23/2021' (Site from Safety).	Lisa Macoy (b) (4)	23 Feb 2021 16:43:48
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'Overnight hours for observation of less than 24hrs. Please clarify if SAE is needed.' (Site from Safety).	Lisa Macoy (b) (4)	23 Feb 2021 16:43:36

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'PCR - NP negative. Report sent 02/23/2021' (Site from Safety).	Lisa Macoy (b) (4) (b) (4)	23 Feb 2021 16:40:32
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:52:05
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:48:49
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 13:48:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Yes (Y)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'No (N)'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Evan'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Anderson'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered '2015 Uppergate Drive'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'Atlanta'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered 'GA'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:21:03
User entered '30323'	System	11 Feb 2021 14:20:41

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
User entered 'US'	System	11 Feb 2021 14:21:09

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:08:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Feb 2021 14:21:09

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:08:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:59:28
User entered '11/Feb/2021 14:21'	System	11 Feb 2021 14:21:09

US3532276

Folder: SAE USA-US077-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:08:32

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.

Audit	User	Time (GMT)
User signature succeeded.	Evan Anderson (b) (4)	03 Apr 2021 04:00:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 16:59:28
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 14:21:09