

US3552140 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:09:21

All time stamps listed in this document are displayed in GMT

US3552140

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:56:36

Generated On: 10 Jun 2021 08:09:21

[Participant ID](#)

US3552140

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

US3552140

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
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	False
Black	True
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) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 17:56:38

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 17:56:38

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	SJOGREN'S SYNDROME
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	FIBROMYELGIA
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	SEASONAL ALLERGIES
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 (7)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	ELECTIVE GASTRIC BYPASS SURGERY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	CHOLESTECTOMY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	BORDERLINE ANEMIA
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Start Year (derived)	1979
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	THROMBOPHLEBITIS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	MIXED CONNECTIVE DISEASE
Start date (dd MMM yyyy)	UN SEP 2004
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)	SEP 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	RAYNAUD'S DISEASE
Start date (dd MMM yyyy)	UN SEP 2004
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)	SEP 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	ANXIETY
Start date (dd MMM yyyy)	UN APR 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)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	BILATERAL CORNEAL INTACS
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	CHOLELITHIASIS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Condition	HERNIATED DISCS L3-L5
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2019
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 11:32
Height (xxx.x)	66.5 in
Weight (xxx.x)	280 lb
BMI (xxx.x)	44.60922 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*) 22 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2013

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:56:38

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

OUT IN COMMUNITY,
GROCERY SHOPPING, FAMILY
VISITS

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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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:56:38

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	GRANDCHILD VISITS FREQUENTLY - 7 YEAR OLD

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 144697

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) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 11:32
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

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)	22 AUG 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 14:04
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:56:38

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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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 13:34 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 13:34

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 AUG 2020
Collection time (00:00-23:59)	12:50 (24 HR)
Collection date and time (derived)	22 AUG 2020 12:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:55	22 AUG 2020 12:55
Nasopharyngeal Swab 2	No		

US3552140

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

22 AUG 2020 14:08

PC Open Date & Time

22 AUG 2020 13:54

PC Close Date & Time

22 AUG 2020 16:24

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐
No ☒

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

PC Time Stamp	22 AUG 2020 21:18
PC Open Date & Time	22 AUG 2020 17:19
PC Close Date & Time	23 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 21:11

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 20:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

26 AUG 2020 05:42

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 23:43

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

28 AUG 2020 03:35

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

29 AUG 2020 00:23

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 14:09

PC Open Date & Time

22 AUG 2020 13:54

PC Close Date & Time

22 AUG 2020 16:24

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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

22 AUG 2020 21:18

PC Open Date & Time

22 AUG 2020 17:19

PC Close Date & Time

23 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 21:13

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 20:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 05:42

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 23:44

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 03:35

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 00:24

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 14:09
PC Open Date & Time	22 AUG 2020 13:54
PC Close Date & Time	22 AUG 2020 16:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 21:19
PC Open Date & Time	22 AUG 2020 17:19
PC Close Date & Time	23 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:13
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 20:41
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 05:42
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

	Yes <input type="radio"/>
PC Time stamp	26 AUG 2020 23:44
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 03:36
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 00:24
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3552140

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:15
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3552140

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☒
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

STILL RECOVERING FROM RECENT RETINAL DETACHMENT SURGERY

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	09:40 (24 HR)
Collection date and time (derived)	21 SEP 2020 09:40

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:45	21 SEP 2020 09:45
Nasopharyngeal Swab 2	No		

US3552140

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552140

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 OCT 2020

Collection time (00:00-23:59)

14:20 (24 HR)

Collection date and time (derived)

16 OCT 2020 14:20

US3552140

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:39

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 07:16:12

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

05 NOV 2020 06:31:08

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 07:16:39

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 00:20:57
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	04 DEC 2020 11:47:01
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 04:54:35

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 17:59:31

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 18:01:00
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	28 DEC 2020 04:09:46
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 05:15:56
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 11:29:11

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 05:32:01

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	26 JAN 2021 21:29:27
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 00:01:46

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 12:04:16

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 03:25:35
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 10:43:23

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 08:28:39
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 20:44:26

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 06:15:22

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 06:07:53

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	01 APR 2021 10:00:14
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 02:19:33

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	13 APR 2021 09:07:46
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 09:54:41

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Date and time of submission	30 APR 2021 14:30:50
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 09:16:43

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 355

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

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

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

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

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

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

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 ☐

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 453

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 516

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

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

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

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

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

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

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 ☐

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 523

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

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

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

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

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

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

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 ☐

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

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11 FEB 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

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18 FEB 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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21 FEB 2022 00:01

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25 FEB 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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28 FEB 2022 00:01

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04 MAR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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07 MAR 2022 00:01

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11 MAR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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14 MAR 2022 00:01

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18 MAR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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21 MAR 2022 00:01

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25 MAR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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28 MAR 2022 00:01

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01 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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04 APR 2022 00:01

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08 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

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15 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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18 APR 2022 00:01

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22 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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25 APR 2022 00:01

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29 APR 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

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20 MAY 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

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27 MAY 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 649

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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03 JUN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 656

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

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10 JUN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

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17 JUN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

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01 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

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08 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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15 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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22 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 705

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

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29 JUL 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 761

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

Patient Cloud Open Date & Time	03 OCT 2022 00:01
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Patient Cloud Close Date & Time	07 OCT 2022 23:59
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US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

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

Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3552140

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:09:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 08:29:00

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

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

Visit date (dd MMM yyyy)	23 MAR 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	VISIT4
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US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:22:48

Generated On: 10 Jun 2021 08:09:21

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552140

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3552140

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	13:45 (24 HR)
Collection date and time (derived)	23 MAR 2021 13:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 19:39:11

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 19:39:11

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552140

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:09:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552140

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

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

Visit date (dd MMM yyyy)	01 FEB 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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US3552140

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:26:45

Generated On: 10 Jun 2021 08:09:21

Date of updated informed consent (<i>dd MMM yyyy</i>)	01 FEB 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>)	01 FEB 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 type="radio"/> Not Administered <input checked="" 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

US3552140

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

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

US3552140

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

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)	01 FEB 2021
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 10:05
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3552140

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

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)	01 FEB 2021
Time of assessment (00:00-23:59)	11:09 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 11:09
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3552140

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 FEB 2021

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

US3552140

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 01 FEB 2021

What was the treatment time? (00:00-23:59) 10:39 (24 HR)

Treatment Date and Time (derived) 01 FEB 2021 10:39

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

What was the frequency of the study treatment dosing? ONCE

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

US3552140

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 FEB 2021
Collection time (00:00-23:59)	09:48 (24 HR)
Collection date and time (derived)	01 FEB 2021 09:48

US3552140

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 FEB 2021
Collection time (00:00 - 23:59)	09:51
Collection Date and Time (derived)	01 FEB 2021 09:51

US3552140

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag	1
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OLD29 Placebo Flag	1
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US3552140

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 27 Feb 2021 17:54:10

Generated On: 10 Jun 2021 08:09:21

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

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 27 Feb 2021 17:54:10

Generated On: 10 Jun 2021 08:09:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	09:44 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 09:44
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 27 Feb 2021 17:54:10

Generated On: 10 Jun 2021 08:09:21

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)	26 FEB 2021
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 10:45
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3552140

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 27 Feb 2021 17:54:10

Generated On: 10 Jun 2021 08:09:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3552140

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 27 Feb 2021 17:54:10

Generated On: 10 Jun 2021 08:09:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 10:15

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

US3552140

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 27 Feb 2021 17:54:10

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 16:54:53

Generated On: 10 Jun 2021 08:09:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552140

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:54:53

Generated On: 10 Jun 2021 08:09:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552140

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3552140

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3552140

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 13:56:21

Generated On: 10 Jun 2021 08:09:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 MAR 2021

Collection time (00:00-23:59)

13:45 (24 HR)

Collection date and time (derived)

23 MAR 2021 13:45

US3552140

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

AEID	USA-US089-2020-MRNA-1273-P30 1000002
Adverse event	RETINAL DETACHMENT OF LEFT EYE
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)	08 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 18:01:31

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

CONTACTED SUBJECT VIA
PHONE AT 9:49 ON 9/10/2020 TO
FOLLOW UP ON NEW
MEDICATION; SUBJECT
SHARED THAT SHE WAS
CURRENTLY EXPERIENCING
NEW VISION
CHANGES/PARTIAL VISION
LOSS IN HER LEFT EYE. SHE
HAD ALREADY CONTACTED
HER OPHTHALMOLOGIST AND
WAS WAITING FOR A RETURN
CALL. SEEN BY
OPHTHALMOLOGIST 9/10,
DIAGNOSED WITH RETINAL
DETACHMENT OF LEFT EYE,
SURGICALLY CORRECTED ON
9/11. THREE NEW
MEDICATIONS STARTED, WILL
UPDATE CON MEDS WHEN
NAMES ARE AVAILABLE.
RECORDS NOT YET AVAILABLE
TO SITE, WILL SEND WHEN WE
HAVE RECEIVED THEM.

WILL FAX THIS AFTERNOON,
NO LAB TESTS PERFORMED.
SUBJECT HAS HISTORY OF
AUTOIMMUNE DISEASE,
UNKNOWN IF THERE IS FAMILY
HISTORY. NO SUSPECTED
CAUSE LISTED IN MEDICAL
RECORDS.

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)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

AEID	USA-US089-2020-MRNA-1273-P30 1000007
Adverse event	HORSESHOE TEAR OF RIGHT EYE
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)	01 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)	06 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 18:01:31

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

SUBJECT REPORTED
RECEIVING LASER EYE
TREATMENT TO FIX A
HORSESHOE TEAR OF RIGHT
EYE. STATES SHE WAS AT HER
EYE DOCTOR FOR AN
APPOINTMENT ABOUT HER
DRY EYES AND UPON EXAM
THEY FOUND THE TEAR AND
WANTED TO FIX IT. NO
COMPLICATIONS
POST-PROCEDURE. HAS TAKEN
IBUPROFEN X2 SINCE
PROCEDURE FOR EYE PAIN
WHICH HAS SINCE RESOLVED.

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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

AEID

Adverse event

FIBROMYALGIA
EXACERBATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

26 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)

04 JAN 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 (4)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

AEID	
Adverse event	LOWER BACK PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 DEC 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)	04 JAN 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 (5)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

AEID	
Adverse event	FALL
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)	11 APR 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)	11 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 type="radio"/> Grade 3/Severe <input checked="" 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 (6)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

AEID	
Adverse event	ABRASION TO R BROW BONE
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)	11 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 16 Apr 2021 18:01:31

Generated On: 10 Jun 2021 08:09:21

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
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) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

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) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication RHEUMATOID

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 (1)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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)	2	
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) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication BUMEX

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (2)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PILOCARPINE

Prophylaxis Yes ☐
No ☒

Indication SJOGREN'S SYNDROME

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2004	
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 (4)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication SAVELLA

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:28:08

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Name of Medication ZOLPIDEM

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication MUSCLE PAIN DUE TO
FIBROMYALGIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 15:28:08

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	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 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)		
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 (7)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication HEALTH PROMOTION

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 (8)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

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

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication NIFEDIPINE ER

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:28:08

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Name of Medication WELLBUTRIN ER

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 SEP 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 (11)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication MOXIFLOXICAN

Prophylaxis Yes ☐
No ☒

Indication RETINAL DETACHMENT

Dose per administration 1

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

If dose unit is Other, specify DROP TO L EYE

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) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 18 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PREDNISOLONE ACETATE

Prophylaxis Yes ☐
No ☒

Indication RETINAL DETACHMENT

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 ☐
Intraocular ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 SEP 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication CYCLOPENTOLATE 1%

Prophylaxis Yes ☐
No ☒

Indication RETINAL DETACHMENT

Dose per administration 1

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

If dose unit is Other, specify DROP TO L EYE

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) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		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) 26 Apr 2021 15:28:08

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Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	EYE PAIN RELATED TO EYE PROCEDURE
Dose per administration	600
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 15:28:08

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	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)	01 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)		02 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 (16)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication CYCLOPENTOLATE 2%

Prophylaxis Yes ☐
No ☒

Indication CRYOTHERAPY OF RIGHT EYE

Dose per administration 1

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

If dose unit is Other, specify DROP IN RIGHT EYE

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) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	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 SOLUTION	
Start date (dd MMM yyyy)	06 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PHENYLEPHRINE 2.5%

Prophylaxis Yes ☐
No ☒

Indication CRYOTHERAPY OF RIGHT EYE

Dose per administration 1

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

If dose unit is Other, specify DROP IN RIGHT EYE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	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 SOLUTION	
Start date (dd MMM yyyy)	06 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication TROPICAMIDE 1%

Prophylaxis Yes ☐
No ☒

Indication CRYOTHERAPY OF RIGHT EYE

Dose per administration 1

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

If dose unit is Other, specify DROP IN RIGHT EYE

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 (18)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	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 SOLUTION	
Start date (dd MMM yyyy)	06 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication LEFLUNOMIDE

Prophylaxis Yes ☐
No ☒

Indication RHEUMATOID ARTHRITIS

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 (20)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 7.5

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 (22)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 DEC 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 (23)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 DEC 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 (25)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PERCOCET [OXYCODINE /
ACETAMINOPHEN]

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication LOWER BACK PAIN

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication TYLENOL #3
[ACETAMINOPHEN/CODEINE]

Prophylaxis Yes ☐
No ☒

Indication INTRAOCULAR SILICONE
IMPLANT REMOVAL - LEFT EYE

Dose per administration 300/30

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 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)		27 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 (28)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication PREDNISONE 2.5%

Prophylaxis Yes ☐
No ☒

Indication LEFT EYE CATARACT IMPLANT

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 ☐
Intraocular ☒

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 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)	4	
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 (29)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication NEVANAC 0.1%

Prophylaxis Yes ☐
No ☒

Indication LEFT EYE CATARACT IMPLANT

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 ☐
Intraocular ☒

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 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)	4	
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 (30)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication MELOXICAM 0.5%

Prophylaxis Yes ☐
No ☒

Indication LEFT EYE CATARACT IMPLANT

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 ☐
Intraocular ☒

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 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)	4	
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 (31)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication DICLOFENAC SODIUM

Prophylaxis Yes ☐
No ☒

Indication FALL RELATED PAIN

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 (31)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication ABRASION TO R BROW BONE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 15:28:08

Generated On: 10 Jun 2021 08:09:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	17 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 06 Apr 2021 15:11:41

Generated On: 10 Jun 2021 08:09:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 SEP 2020	LEFT EYE VITRECTOMY MEMBRANECTOMY [RETINAL DETACHMENT REPAIR]	Adverse Event	
01 OCT 2020	LASER PHOTOCOAGULATION REPAIR OF RIGHT RETINAL HORSESHOE TEAR	Adverse Event	
06 OCT 2020	CRYOTHERAPY OF RIGHT EYE	Adverse Event	
26 JAN 2021	INTRAOCULAR SILICONE IMPLANT REMOVAL - LEFT EYE	Adverse Event	
26 MAR 2021	LEFT EYE CATARACT IMPLANT	Medical History	

US3552140

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

Date of dosing discontinuation (dd MMM yyyy) 21 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

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

SAE #2

US3552140

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:09:21

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/SEP/2020 09:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/SEP/2020 07:26
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

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/SEP/2020 11:42
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

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/OCT/2020 08:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Feb 2021 17:56:37

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/NOV/2020 09:54
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

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/OCT/2020 13:26
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

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	13/OCT/2020 16:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/OCT/2020 08:26
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

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/NOV/2020 09:54
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

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/NOV/2020 13:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 21 Feb 2021 17:56:38

Generated On: 10 Jun 2021 08:09:21

SAEID	USA-US089-2020-MRNA-1273-P301000007
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	SHARON
Investigator's Last Name	FREY
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/JAN/2021 17:28
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

US3552140 (Prod: Saint Louis University)

US3552140

Form: Participant Creation

Generated On: 10 Jun 2021 08:09:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'US3552140'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:04:09

US3552140

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:12

US3552140

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:04:11

US3552140

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:12

US3552140

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'SCRN'	System	24 Aug 2020 12:05:12

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered (b) (6) 1961'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:04:12

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '59'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'YEARS'	System	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '59'	System	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Female (F)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:09:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:05:36

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	(b) (4), (b) (6)	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Aug 2020'	System	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2020'	System	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4), (b) (6)	22 Aug 2020 18:05:03

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:04:11

US3552140

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:09:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'l'	System	22 Aug 2020 18:05:11

US3552140

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Aug 2020 18:05:11

US3552140

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:09:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:07:59

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:50:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:39:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:39:51
Data point term sent to Coder	System	01 Oct 2020 19:39:24
Query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:38:53
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:38:42
User entered 'generalized RHEUMATOID ARTHRITIS' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:38:42
User opened query 'Per DM CLR: Please specify the location of RHEUMATOID ARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:28:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:10:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:10:39

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Aug 2020 12:09:22
User entered 'rheumatoid arthritis'	Stanley Doublin (b) (4)	24 Aug 2020 12:08:40
	(b) (4)	

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2015'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2015'	System	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2015'	System	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:08:40

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
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)	24 Aug 2020 12:10:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:10:40
Data point term sent to Coder	System	24 Aug 2020 12:09:23
User entered 'hypertension'	Stanley Doublin (b) (4)	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2012'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2012'	System	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2012'	System	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:08:54

US3552140

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Connective tissue disorders (excl congenital), HLT: Connective tissue disorders NEC, PT: Sjogren's syndrome, LLT: Sjogren's syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:11:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:11:29
Data point term sent to Coder	System	24 Aug 2020 12:10:25
User entered 'sjogren's syndrome'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:30

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2004'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:30

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:30

US3552140

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
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	24 Aug 2020 12:09:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	24 Aug 2020 12:09:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	24 Aug 2020 12:09:30
	Stanley Dublin (b) (4)	24 Aug 2020 12:09:30
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:30

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:30

US3552140

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2004'	System	24 Aug 2020 12:09:30

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2004'	System	24 Aug 2020 12:09:30

US3552140

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:09:30

US3552140

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:09:30

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 20:20:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 20:20:36
Data point term sent to Coder	System	24 Aug 2020 12:10:24
User entered 'fibromyelgia'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2008'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2008'	System	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2008'	System	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:09:57

US3552140

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:11:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:11:29
Data point term sent to Coder	System	24 Aug 2020 12:10:24
User entered 'insomnia'	Stanley Dublin (b) (4)	24 Aug 2020 12:10:14

US3552140

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2015'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:14

US3552140

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:14

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:14

US3552140

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:14

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:14

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2015'	System	24 Aug 2020 12:10:14

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2015'	System	24 Aug 2020 12:10:14

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:10:14

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:10:14

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
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.	(b) (4) Coder Import (b) (4)	24 Aug 2020 12:12:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:12:32
Data point term sent to Coder	System	24 Aug 2020 12:11:26
User entered 'seasonal allergies'	Stanley Doublin (b) (4)	24 Aug 2020 12:10:29
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2000'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:29

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:29

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:29

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:29

US3552140

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:10:29

US3552140

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2000'	System	24 Aug 2020 12:10:29

US3552140

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2000'	System	24 Aug 2020 12:10:29

US3552140

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:10:29

US3552140

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:10:29

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:30:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:30:33
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 10:53:48
Data point term sent to Coder	System	02 Oct 2020 18:57:20
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated per query request' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 18:57:04
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 18:56:53
User entered 'Elective GASTRIC BYPASS SURGERY' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 18:56:53
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:28:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:12:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:12:32
Data point term sent to Coder	System	24 Aug 2020 12:11:25
User entered 'gastric bypass surgery'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:17

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2000'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:17

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:17

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	24 Aug 2020 12:11:59
User entered 'Yes (Y)'	(b) (4)	
	Stanley Dublin (b) (4)	24 Aug 2020 12:11:17
	(b) (4)	

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2000' reason for change:	(b) (4)	
Data Entry Error	Stanley Dublin (b) (4)	24 Aug 2020 12:11:59
User entered empty.	(b) (4)	
	Stanley Dublin (b) (4)	24 Aug 2020 12:11:17
	(b) (4)	

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:17

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2000'	System	24 Aug 2020 12:11:17

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2000'	System	24 Aug 2020 12:11:17

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2000'	System	24 Aug 2020 12:11:59
User entered empty.	System	24 Aug 2020 12:11:17

US3552140

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2000'	System	24 Aug 2020 12:11:59
User entered empty.	System	24 Aug 2020 12:11:17

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:58:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:28:33
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:29:14
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) (b) (4)	24 Aug 2020 12:13:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:13:34
Data point term sent to Coder	System	24 Aug 2020 12:12:27
User entered 'cholestectomy'	Stanley Doublin (b) (4) (b) (4)	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 1999'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 1999'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 1999'	System	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '1999'	System	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 1999'	System	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '1999'	System	24 Aug 2020 12:11:46

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:11:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:11:38
Data point term sent to Coder	System	24 Aug 2020 12:13:27
User entered 'borderline anemia'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 1979'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 1979'	System	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '1979'	System	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:12:35

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Thrombophlebitis, LLT: Thrombophlebitis - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:14:37
Data point term sent to Coder	(b) (4)	
User entered 'thrombophlebitis'	Coder Import (b) (4)	24 Aug 2020 12:14:37
	(b) (4)	
	System	24 Aug 2020 12:13:29
	Stanley Dublin (b) (4)	24 Aug 2020 12:13:16
	(b) (4)	

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2018'	System	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2018'	System	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2019'	System	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2019'	System	24 Aug 2020 12:13:16

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:57:36
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:33:09
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:29:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Spinal fusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:15:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:15:38
Data point term sent to Coder	System	24 Aug 2020 12:14:30
User entered 'spinal fusion'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un Jan 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un Jan 2019'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2019'	System	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2019'	System	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2019'	System	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2019'	System	24 Aug 2020 12:13:38

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 12:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:16:43
Data point term sent to Coder	System	24 Aug 2020 12:15:31
User entered 'menopause'	Stanley Doublin (b) (4)	24 Aug 2020 12:15:05
	(b) (4)	

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2013'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2013'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2013'	System	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2013'	System	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2013'	System	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2013'	System	24 Aug 2020 12:15:05

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
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 replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 13:31:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 13:31:46
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:46:01
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated per query request' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:35:18
Data point term sent to Coder	System	01 Oct 2020 19:35:15
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:35:03
User entered 'LEFT KNEE REPLACEMENT secondary to rheumatoid arthritis' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:35:03
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:29:48
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 replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:16:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:16:44
Data point term sent to Coder	System	24 Aug 2020 12:15:34

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
User entered 'left knee replacement'	Stanley Dublin (b) (4)	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2018'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2018'	System	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2018'	System	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2018'	System	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2018'	System	24 Aug 2020 12:15:31

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Connective tissue disorders (excl congenital), HLT: Connective tissue disorders NEC, PT: Mixed connective tissue disease, LLT: Mixed connective tissue disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:14:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:14:22
Data point term sent to Coder	System	24 Aug 2020 19:02:26
User entered 'MIXED CONNECTIVE disease' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	24 Aug 2020 19:01:42
Data point term sent to Coder	System	24 Aug 2020 12:16:35
User entered 'mixed connective'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un Sep 2004'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Sep 2004'	System	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2004'	System	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:15:53

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Vascular disorders, HLT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Raynaud's phenomenon, LLT: Raynaud's disease - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 12:18:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 12:18:30
Data point term sent to Coder	System	24 Aug 2020 12:17:37
User entered 'raynaud's disease'	Stanley Doublin (b) (4)	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un Sep 2004'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Sep 2004'	System	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2004'	System	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:16:40

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema, LLT: Pitting edema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:29:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:29:38
Data point term sent to Coder	System	24 Aug 2020 12:17:38
User entered 'bilateral pitting edema'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2012'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2012'	System	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2012'	System	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Aug 2020 12:17:30

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 15:13:43
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 15:13:43
Data point term sent to Coder	System	10 Sep 2020 15:13:10
User entered 'Anxiety'	Heather Douds (b) (4) (b) (4)	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'un Apr 2019'	Heather Douds (b) (4) (b) (4)	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '0'	Heather Douds (b) (4) (b) (4)	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Heather Douds (b) (4) (b) (4)	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '0'	Heather Douds (b) (4) (b) (4)	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Apr 2019'	System	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2019'	System	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	10 Sep 2020 15:12:56

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:05:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Corneal implant, LLT: Corneal implant - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 11:47:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 11:47:29
Data point term sent to Coder	System	02 Oct 2020 19:02:33
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 19:01:40
User entered 'BILATERAL CORNEAL intacs' reason for change: New Information	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 19:01:40
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'will ask subject and update data once received' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:38:06
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:32:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Corneal implant, LLT: Corneal implant - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:15:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Sep 2020 05:15:43
Data point term sent to Coder	System	12 Sep 2020 15:30:04
User entered 'bilateral corneal rings'	Heather Douds (b) (4) (b) (4)	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 1994'	Heather Douds (b) (4) (b) (4)	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '0'	Heather Douds (b) (4) (b) (4)	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Heather Douds (b) (4) (b) (4)	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '0'	Heather Douds (b) (4) (b) (4)	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 1994'	System	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '1994'	System	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	12 Sep 2020 15:29:06

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 19:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 19:31:47
Data point term sent to Coder	System	01 Oct 2020 19:31:04
User entered 'cholelithiasis'	Cassandra Zehenny (b) (4)	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 1999'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 1999'	System	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '1999'	System	01 Oct 2020 19:30:51

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Lumbar disc herniation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 05:31:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 05:31:39
Data point term sent to Coder	System	01 Oct 2020 19:34:13
User entered 'herniated discs L3-L5'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'un Jan 2019'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'Jan 2019'	System	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '2019'	System	01 Oct 2020 19:33:55

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Left cataract - version MedDRA\\23.0.	(b) (4) Codor Import (b) (4)	24 Mar 2021 14:59:36
User coded data point as Term Coded data point by User: Codor System - version MedDRA\\23.0.	Codor Import (b) (4)	24 Mar 2021 14:59:36
Data point term sent to Codor System	System	24 Mar 2021 14:59:00
User entered 'LEFT EYE CATARACT' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	24 Mar 2021 14:58:59
Data point term sent to Codor System	System	24 Mar 2021 14:58:58
User entered 'left eye cataracts'	Cassandra Zehenny (b) (4)	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:56:21
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:56:21
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:56:21
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:56:21
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	29 Mar 2021 13:56:21
User entered '0'	Cassandra Zehenny (b) (4) (b) (4)	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered empty.	System	24 Mar 2021 14:58:54

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '11:32'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered '22 Aug 2020 11:32'	System	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '66.5' in	(b) (4) Stanley Dublin (b) (4)	24 Aug 2020 12:19:15
DataPoint set to visible.	(b) (4) System	22 Aug 2020 18:05:11

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '280' lb	(b) (4) Stanley Dublin (b) (4)	24 Aug 2020 12:19:15
DataPoint set to visible.	(b) (4) System	22 Aug 2020 18:05:11

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
Amendment Manager: User entered '44.60922'	System	17 Sep 2020 00:20:10
User entered '44.6'	System	24 Aug 2020 12:19:15
DataPoint set to visible.	System	22 Aug 2020 18:05:11

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'kg/m2'	System	24 Aug 2020 12:19:15
DataPoint set to visible.	System	22 Aug 2020 18:05:11

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'bpm'	System	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'breaths/min'	System	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'mmHg'	System	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User entered 'mmHg'	System	24 Aug 2020 12:19:15

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08

US3552140

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08

US3552140

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:39

US3552140

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:19:39

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:20:32

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:09:21

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:20:32

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:09:21

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 06:18:05
Query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' answered with 'updated per query request' (Site from DM).	Heather Douds (b) (4) (b) (4)	04 Sep 2020 15:04:27
User opened query 'Per CDM: "If No, what is the reason" is "Post-menopausal"; however the condition is not recorded in "Medical History" form. Please refer to page 22 of CCGs, and update all relevant medical conditions in "Medical History" form. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 08:58:39
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stanley Doublin (b) (4) (b) (4)	24 Aug 2020 12:20:32

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:09:21

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:20:32

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:20:32

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:09:21

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:20:32

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:09:21

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'un UNK 2013'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:20:32

US3552140

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:09:21

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:20:32

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

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 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

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 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'out in community, grocery shopping, family visits'	(b) (4) Stanley Dublin (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '0'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'l'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:09:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:12:08
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'GRANDCHILD VISITS FREQUENTLY - 7 YEAR OLD' reason for change:	(b) (4)	
Data Entry Error	Stanley Doublin (b) (4)	24 Aug 2020 12:23:02
User entered 'grandchildred visits frequently - 7 year old'	(b) (4)	24 Aug 2020 12:22:30

US3552140

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:23:13

US3552140

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:23:13

US3552140

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:23:13

US3552140

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'VISIT1'	System	24 Aug 2020 12:23:13

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:04:17

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '144697'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:04:17

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 18:04:17

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:23:26

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:23:26

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:23:26

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:23:26

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:23:26

US3552140

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:09:21

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 17:22:17
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:20:44

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '11:32' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	24 Aug 2020 19:49:40
User entered '12:32'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '22 Aug 2020 11:32'	System	24 Aug 2020 19:49:40
User entered '22 Aug 2020 12:32'	System	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '98.3' F	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '90'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'bpm'	System	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '16'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'breaths/min'	System	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '131'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'mmHg'	System	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '91'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'mmHg'	System	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:24:50

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '14:04'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '22 Aug 2020 14:04'	System	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '98.3' F	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 12:25:30
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Aug 2020 12:25:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:30
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 12:25:23
User entered empty.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '90'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'bpm'	System	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '18'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'breaths/min'	System	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '136'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'mmHg'	System	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '94'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'mmHg'	System	24 Aug 2020 12:25:23

US3552140

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:40

US3552140

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:25:40

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4), (b) (6)	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '13:34' reason for change: Data Entry Error	System	22 Aug 2020 18:41:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	22 Aug 2020 18:41:13
User entered '13:' (non-conformant).	System	22 Aug 2020 18:41:00
	(b) (4), (b) (6)	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '22 Aug 2020 13:34'	System	22 Aug 2020 18:41:13
User entered '22 Aug 2020 13:' (non-conformant).	System	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'ONCE'	System	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 18:41:00

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:02

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:02

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '12:50'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:02

US3552140

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '22 Aug 2020 12:50'	System	24 Aug 2020 12:26:02

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '22 Aug 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:18

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Doublin (b) (4) (b) (4)	24 Aug 2020 12:26:18

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:18

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '12:55'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:18

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '22 Aug 2020 12:55'	System	24 Aug 2020 12:26:18

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:22

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:22

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4)	24 Aug 2020 12:26:22

US3552140

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	24 Aug 2020 12:26:22

US3552140

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:55:13

US3552140

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'l'	System	29 Aug 2020 19:55:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:14', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aafa6290-5ac0-4816-b507-ed90d9645df5'	System	22 Aug 2020 19:08:36
User entered 'Yes (Y)'	System	22 Aug 2020 19:08:36

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aafa6290-5ac0-4816-b507-ed90d9645df5'	System	22 Aug 2020 19:08:36
User entered '98.3'	System	22 Aug 2020 19:08:36

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:27', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aafa6290-5ac0-4816-b507-ed90d9645df5'	System	22 Aug 2020 19:08:36
User entered 'No (N)'	System	22 Aug 2020 19:08:36

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:33', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aafa6290-5ac0-4816-b507-ed90d9645df5'	System	22 Aug 2020 19:08:36
User entered '22 Aug 2020 14:08'	System	22 Aug 2020 19:08:36

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 13:54'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 16:24'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:17:49', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d59ebb8-c835-49c5-8c28-755c81d0c9df'	System	23 Aug 2020 02:18:10
User entered 'Yes (Y)'	System	23 Aug 2020 02:18:10

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:17:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d59ebb8-c835-49c5-8c28-755c81d0c9df'	System	23 Aug 2020 02:18:10
User entered '97.8'	System	23 Aug 2020 02:18:10

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:01', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d59ebb8-c835-49c5-8c28-755c81d0c9df'	System	23 Aug 2020 02:18:10
User entered 'No (N)'	System	23 Aug 2020 02:18:10

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d59ebb8-c835-49c5-8c28-755c81d0c9df'	System	23 Aug 2020 02:18:10
User entered '22 Aug 2020 21:18'	System	23 Aug 2020 02:18:10

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 17:19'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 2'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:11:41', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '179918e4-5550-48e6-b62e-21f8b0de1769'	System	24 Aug 2020 02:12:04
User entered 'Yes (Y)'	System	24 Aug 2020 02:12:04

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:11:49', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '179918e4-5550-48e6-b62e-21f8b0de1769'	System	24 Aug 2020 02:12:04
User entered '97.8'	System	24 Aug 2020 02:12:04

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:11:52', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '179918e4-5550-48e6-b62e-21f8b0de1769'	System	24 Aug 2020 02:12:04
User entered 'No (N)'	System	24 Aug 2020 02:12:04

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:11:58', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '179918e4-5550-48e6-b62e-21f8b0de1769'	System	24 Aug 2020 02:12:04
User entered '23 Aug 2020 21:11'	System	24 Aug 2020 02:12:04

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 3'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:04', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '174fe3da-5840-486c-a5ad-08dee4613e1b'	System	25 Aug 2020 01:40:21
User entered 'Yes (Y)'	System	25 Aug 2020 01:40:21

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:11', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '174fe3da-5840-486c-a5ad-08dee4613e1b'	System	25 Aug 2020 01:40:21
User entered '97.2'	System	25 Aug 2020 01:40:21

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:14', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '174fe3da-5840-486c-a5ad-08dee4613e1b'	System	25 Aug 2020 01:40:21
User entered 'No (N)'	System	25 Aug 2020 01:40:21

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:18', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '174fe3da-5840-486c-a5ad-08dee4613e1b'	System	25 Aug 2020 01:40:21
User entered '24 Aug 2020 20:40'	System	25 Aug 2020 01:40:21

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 4'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:41:37', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '00753a79-26dd-46d9-adad-4d78119493a5'	System	26 Aug 2020 10:42:09
User entered 'Yes (Y)'	System	26 Aug 2020 10:42:09

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:41:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '00753a79-26dd-46d9-adad-4d78119493a5'	System	26 Aug 2020 10:42:09
User entered '97.7'	System	26 Aug 2020 10:42:09

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:01', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '00753a79-26dd-46d9-adad-4d78119493a5'	System	26 Aug 2020 10:42:09
User entered 'No (N)'	System	26 Aug 2020 10:42:09

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:04', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '00753a79-26dd-46d9-adad-4d78119493a5'	System	26 Aug 2020 10:42:09
User entered '26 Aug 2020 05:42'	System	26 Aug 2020 10:42:09

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 5'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:43:30', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd5d7f432-ebba-4c94-ac95-3a475d640d7d'	System	27 Aug 2020 04:44:02
User entered 'Yes (Y)'	System	27 Aug 2020 04:44:02

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:43:50', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd5d7f432-ebba-4c94-ac95-3a475d640d7d'	System	27 Aug 2020 04:44:02
User entered '97.9'	System	27 Aug 2020 04:44:02

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:43:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd5d7f432-ebba-4c94-ac95-3a475d640d7d'	System	27 Aug 2020 04:44:02
User entered 'No (N)'	System	27 Aug 2020 04:44:02

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:43:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd5d7f432-ebba-4c94-ac95-3a475d640d7d'	System	27 Aug 2020 04:44:02
User entered '26 Aug 2020 23:43'	System	27 Aug 2020 04:44:02

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 6'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd358dc2a-99c2-416c-8ddf-a28b418edc4b'	System	28 Aug 2020 08:35:31
User entered 'Yes (Y)'	System	28 Aug 2020 08:35:31

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd358dc2a-99c2-416c-8ddf-a28b418edc4b'	System	28 Aug 2020 08:35:31
User entered '96.6'	System	28 Aug 2020 08:35:31

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:20', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd358dc2a-99c2-416c-8ddf-a28b418edc4b'	System	28 Aug 2020 08:35:31
User entered 'No (N)'	System	28 Aug 2020 08:35:31

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd358dc2a-99c2-416c-8ddf-a28b418edc4b'	System	28 Aug 2020 08:35:31
User entered '28 Aug 2020 03:35'	System	28 Aug 2020 08:35:31

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 7'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:32', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ef53b37-0288-414b-93fb-6ddaa8496977'	System	29 Aug 2020 05:23:49
User entered 'Yes (Y)'	System	29 Aug 2020 05:23:49

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:39', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ef53b37-0288-414b-93fb-6ddaa8496977'	System	29 Aug 2020 05:23:49
User entered '97.6'	System	29 Aug 2020 05:23:49

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:44', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ef53b37-0288-414b-93fb-6ddaa8496977'	System	29 Aug 2020 05:23:49
User entered 'No (N)'	System	29 Aug 2020 05:23:49

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ef53b37-0288-414b-93fb-6ddaa8496977'	System	29 Aug 2020 05:23:49
User entered '29 Aug 2020 00:23'	System	29 Aug 2020 05:23:49

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:43', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788'	System	22 Aug 2020 19:09:01
User entered 'None (1)'	System	22 Aug 2020 19:09:01

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:47', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788'	System	22 Aug 2020 19:09:01
User entered 'No (N)'	System	22 Aug 2020 19:09:01

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788'	System	22 Aug 2020 19:09:01
User entered 'No (N)'	System	22 Aug 2020 19:09:01

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:08:55', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788'	System	22 Aug 2020 19:09:01
User entered 'None (1)'	System	22 Aug 2020 19:09:01

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '79a0bdd1-d8ef-4682-9c1a-231d3119f788'	System	22 Aug 2020 19:09:01
User entered '22 Aug 2020 14:09'	System	22 Aug 2020 19:09:01

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 13:54'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 16:24'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96'	System	23 Aug 2020 02:18:51
User entered 'None (1)'	System	23 Aug 2020 02:18:51

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:37', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96'	System	23 Aug 2020 02:18:51
User entered 'No (N)'	System	23 Aug 2020 02:18:51

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:41', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96'	System	23 Aug 2020 02:18:51
User entered 'No (N)'	System	23 Aug 2020 02:18:51

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:44', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96'	System	23 Aug 2020 02:18:51
User entered 'None (1)'	System	23 Aug 2020 02:18:51

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:47', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5a9a960f-efcf-48b9-86c1-e0a20acc6c96'	System	23 Aug 2020 02:18:51
User entered '22 Aug 2020 21:18'	System	23 Aug 2020 02:18:51

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 17:19'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 2'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:12:30', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed'	System	24 Aug 2020 02:14:05
User entered 'None (1)'	System	24 Aug 2020 02:14:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:12:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed'	System	24 Aug 2020 02:14:05
User entered 'No (N)'	System	24 Aug 2020 02:14:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:09', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed'	System	24 Aug 2020 02:14:05
User entered 'No (N)'	System	24 Aug 2020 02:14:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed'	System	24 Aug 2020 02:14:05
User entered 'None (1)'	System	24 Aug 2020 02:14:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'afcea38a-d286-4330-9033-18f2045f0bed'	System	24 Aug 2020 02:14:05
User entered '23 Aug 2020 21:13'	System	24 Aug 2020 02:14:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 3'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:40', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497'	System	25 Aug 2020 01:41:02
User entered 'None (1)'	System	25 Aug 2020 01:41:02

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:43', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497'	System	25 Aug 2020 01:41:02
User entered 'No (N)'	System	25 Aug 2020 01:41:02

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497'	System	25 Aug 2020 01:41:02
User entered 'No (N)'	System	25 Aug 2020 01:41:02

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:55', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497'	System	25 Aug 2020 01:41:02
User entered 'None (1)'	System	25 Aug 2020 01:41:02

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:40:58', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2ef3b729-0d81-485a-be6b-b67f4d919497'	System	25 Aug 2020 01:41:02
User entered '24 Aug 2020 20:40'	System	25 Aug 2020 01:41:02

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 4'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd'	System	26 Aug 2020 10:42:30
User entered 'None (1)'	System	26 Aug 2020 10:42:30

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:13', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd'	System	26 Aug 2020 10:42:30
User entered 'No (N)'	System	26 Aug 2020 10:42:30

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd'	System	26 Aug 2020 10:42:30
User entered 'No (N)'	System	26 Aug 2020 10:42:30

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:22', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd'	System	26 Aug 2020 10:42:30
User entered 'None (1)'	System	26 Aug 2020 10:42:30

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:25', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '29b7b93a-5528-4697-b43d-7a07cd05ecbd'	System	26 Aug 2020 10:42:30
User entered '26 Aug 2020 05:42'	System	26 Aug 2020 10:42:30

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 5'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481'	System	27 Aug 2020 04:44:19
User entered 'None (1)'	System	27 Aug 2020 04:44:19

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:05', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481'	System	27 Aug 2020 04:44:19
User entered 'No (N)'	System	27 Aug 2020 04:44:19

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:07', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481'	System	27 Aug 2020 04:44:19
User entered 'No (N)'	System	27 Aug 2020 04:44:19

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481'	System	27 Aug 2020 04:44:19
User entered 'None (1)'	System	27 Aug 2020 04:44:19

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'b709a0b5-92fa-4fbb-bf0c-165367d65481'	System	27 Aug 2020 04:44:19
User entered '26 Aug 2020 23:44'	System	27 Aug 2020 04:44:19

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 6'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:29', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2'	System	28 Aug 2020 08:35:42
User entered 'None (1)'	System	28 Aug 2020 08:35:42

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:32', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2'	System	28 Aug 2020 08:35:42
User entered 'No (N)'	System	28 Aug 2020 08:35:42

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2'	System	28 Aug 2020 08:35:42
User entered 'No (N)'	System	28 Aug 2020 08:35:42

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:38', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2'	System	28 Aug 2020 08:35:42
User entered 'None (1)'	System	28 Aug 2020 08:35:42

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:40', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'a2ba6c1b-ecfe-4b02-b3fa-c7123070e9d2'	System	28 Aug 2020 08:35:42
User entered '28 Aug 2020 03:35'	System	28 Aug 2020 08:35:42

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 7'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3'	System	29 Aug 2020 05:24:05
User entered 'None (1)'	System	29 Aug 2020 05:24:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:55', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3'	System	29 Aug 2020 05:24:05
User entered 'No (N)'	System	29 Aug 2020 05:24:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3'	System	29 Aug 2020 05:24:05
User entered 'No (N)'	System	29 Aug 2020 05:24:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:23:59', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3'	System	29 Aug 2020 05:24:05
User entered 'None (1)'	System	29 Aug 2020 05:24:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '8d39c997-7236-4cc7-8cb4-3c8ed32293b3'	System	29 Aug 2020 05:24:05
User entered '29 Aug 2020 00:24'	System	29 Aug 2020 05:24:05

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:05', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa'	System	22 Aug 2020 19:09:39
User entered 'None (0)'	System	22 Aug 2020 19:09:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa'	System	22 Aug 2020 19:09:39
User entered 'None (0)'	System	22 Aug 2020 19:09:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:13', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa'	System	22 Aug 2020 19:09:39
User entered 'None (0)'	System	22 Aug 2020 19:09:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa'	System	22 Aug 2020 19:09:39
User entered 'None (0)'	System	22 Aug 2020 19:09:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:20', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa'	System	22 Aug 2020 19:09:39
User entered 'None (0)'	System	22 Aug 2020 19:09:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa'	System	22 Aug 2020 19:09:39
User entered 'None (0)'	System	22 Aug 2020 19:09:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:31', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa'	System	22 Aug 2020 19:09:39
User entered 'No (N)'	System	22 Aug 2020 19:09:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T14:09:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3b2d2b7c-b8c4-498d-93d9-f70650b6b6fa'	System	22 Aug 2020 19:09:39
User entered '22 Aug 2020 14:09'	System	22 Aug 2020 19:09:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 13:54'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 16:24'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:52', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934'	System	23 Aug 2020 02:19:24
User entered 'None (0)'	System	23 Aug 2020 02:19:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934'	System	23 Aug 2020 02:19:24
User entered 'None (0)'	System	23 Aug 2020 02:19:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:18:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934'	System	23 Aug 2020 02:19:24
User entered 'None (0)'	System	23 Aug 2020 02:19:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934'	System	23 Aug 2020 02:19:24
User entered 'None (0)'	System	23 Aug 2020 02:19:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:04', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934'	System	23 Aug 2020 02:19:24
User entered 'None (0)'	System	23 Aug 2020 02:19:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934'	System	23 Aug 2020 02:19:24
User entered 'None (0)'	System	23 Aug 2020 02:19:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:18', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934'	System	23 Aug 2020 02:19:24
User entered 'No (N)'	System	23 Aug 2020 02:19:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-22T21:19:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '71c4d341-0787-4c3b-a948-52b85a938934'	System	23 Aug 2020 02:19:24
User entered '22 Aug 2020 21:19'	System	23 Aug 2020 02:19:24

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '22 Aug 2020 17:19'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 2'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092'	System	24 Aug 2020 02:14:18
User entered 'None (0)'	System	24 Aug 2020 02:14:18

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:31', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092'	System	24 Aug 2020 02:14:18
User entered 'None (0)'	System	24 Aug 2020 02:14:18

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092'	System	24 Aug 2020 02:14:18
User entered 'None (0)'	System	24 Aug 2020 02:14:18

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:36', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092'	System	24 Aug 2020 02:14:18
User entered 'None (0)'	System	24 Aug 2020 02:14:18

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:38', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092'	System	24 Aug 2020 02:14:18
User entered 'None (0)'	System	24 Aug 2020 02:14:18

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:40', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092'	System	24 Aug 2020 02:14:18
User entered 'None (0)'	System	24 Aug 2020 02:14:18

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092'	System	24 Aug 2020 02:14:18
User entered 'No (N)'	System	24 Aug 2020 02:14:18

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-23T21:13:55', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'fcd00f71-f2d7-4362-9ed0-0f5db61c3092'	System	24 Aug 2020 02:14:18
User entered '23 Aug 2020 21:13'	System	24 Aug 2020 02:14:18

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 3'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4'	System	25 Aug 2020 01:41:31
User entered 'None (0)'	System	25 Aug 2020 01:41:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4'	System	25 Aug 2020 01:41:31
User entered 'None (0)'	System	25 Aug 2020 01:41:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:08', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4'	System	25 Aug 2020 01:41:31
User entered 'None (0)'	System	25 Aug 2020 01:41:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:11', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4'	System	25 Aug 2020 01:41:31
User entered 'None (0)'	System	25 Aug 2020 01:41:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:14', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4'	System	25 Aug 2020 01:41:31
User entered 'None (0)'	System	25 Aug 2020 01:41:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4'	System	25 Aug 2020 01:41:31
User entered 'None (0)'	System	25 Aug 2020 01:41:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4'	System	25 Aug 2020 01:41:31
User entered 'No (N)'	System	25 Aug 2020 01:41:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-24T20:41:27', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3c25950c-2537-4601-b108-c272e4de02a4'	System	25 Aug 2020 01:41:31
User entered '24 Aug 2020 20:41'	System	25 Aug 2020 01:41:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 4'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912'	System	26 Aug 2020 10:42:57
User entered 'None (0)'	System	26 Aug 2020 10:42:57

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:36', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912'	System	26 Aug 2020 10:42:57
User entered 'None (0)'	System	26 Aug 2020 10:42:57

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:39', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912'	System	26 Aug 2020 10:42:57
User entered 'None (0)'	System	26 Aug 2020 10:42:57

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:42', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912'	System	26 Aug 2020 10:42:57
User entered 'None (0)'	System	26 Aug 2020 10:42:57

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912'	System	26 Aug 2020 10:42:57
User entered 'None (0)'	System	26 Aug 2020 10:42:57

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:48', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912'	System	26 Aug 2020 10:42:57
User entered 'None (0)'	System	26 Aug 2020 10:42:57

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:52', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912'	System	26 Aug 2020 10:42:57
User entered 'No (N)'	System	26 Aug 2020 10:42:57

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T05:42:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1caeb5f0-4911-4838-8727-da90ac242912'	System	26 Aug 2020 10:42:57
User entered '26 Aug 2020 05:42'	System	26 Aug 2020 10:42:57

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 5'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829'	System	27 Aug 2020 04:44:39
User entered 'None (0)'	System	27 Aug 2020 04:44:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:18', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829'	System	27 Aug 2020 04:44:39
User entered 'None (0)'	System	27 Aug 2020 04:44:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:20', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829'	System	27 Aug 2020 04:44:39
User entered 'None (0)'	System	27 Aug 2020 04:44:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:22', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829'	System	27 Aug 2020 04:44:39
User entered 'None (0)'	System	27 Aug 2020 04:44:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829'	System	27 Aug 2020 04:44:39
User entered 'None (0)'	System	27 Aug 2020 04:44:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:27', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829'	System	27 Aug 2020 04:44:39
User entered 'None (0)'	System	27 Aug 2020 04:44:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:33', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829'	System	27 Aug 2020 04:44:39
User entered 'Yes (Y)'	System	27 Aug 2020 04:44:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-26T23:44:35', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'cfd16e47-ccb5-4813-bbc5-d4f95bfd5829'	System	27 Aug 2020 04:44:39
User entered '26 Aug 2020 23:44'	System	27 Aug 2020 04:44:39

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 6'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccf8b1165c'	System	28 Aug 2020 08:36:11
User entered 'None (0)'	System	28 Aug 2020 08:36:11

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:48', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c'	System	28 Aug 2020 08:36:11
User entered 'None (0)'	System	28 Aug 2020 08:36:11

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c'	System	28 Aug 2020 08:36:11
User entered 'None (0)'	System	28 Aug 2020 08:36:11

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:53', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccf8b1165c'	System	28 Aug 2020 08:36:11
User entered 'None (0)'	System	28 Aug 2020 08:36:11

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccf8b1165c'	System	28 Aug 2020 08:36:11
User entered 'None (0)'	System	28 Aug 2020 08:36:11

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:35:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccf8b1165c'	System	28 Aug 2020 08:36:11
User entered 'None (0)'	System	28 Aug 2020 08:36:11

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:36:03', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c'	System	28 Aug 2020 08:36:11
User entered 'No (N)'	System	28 Aug 2020 08:36:11

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-28T03:36:09', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3f2b9ac5-e88c-4773-b059-cccfd8b1165c'	System	28 Aug 2020 08:36:11
User entered '28 Aug 2020 03:36'	System	28 Aug 2020 08:36:11

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 7'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a'	System	29 Aug 2020 05:24:31
User entered 'None (0)'	System	29 Aug 2020 05:24:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a'	System	29 Aug 2020 05:24:31
User entered 'None (0)'	System	29 Aug 2020 05:24:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a'	System	29 Aug 2020 05:24:31
User entered 'None (0)'	System	29 Aug 2020 05:24:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:15', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a'	System	29 Aug 2020 05:24:31
User entered 'None (0)'	System	29 Aug 2020 05:24:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a'	System	29 Aug 2020 05:24:31
User entered 'None (0)'	System	29 Aug 2020 05:24:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:19', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a'	System	29 Aug 2020 05:24:31
User entered 'None (0)'	System	29 Aug 2020 05:24:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a'	System	29 Aug 2020 05:24:31
User entered 'No (N)'	System	29 Aug 2020 05:24:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-08-29T00:24:26', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'aa384af4-14f2-4e6a-b803-1119db1f723a'	System	29 Aug 2020 05:24:31
User entered '29 Aug 2020 00:24'	System	29 Aug 2020 05:24:31

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 18:41:13

US3552140

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:09:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:55:28

US3552140

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '29 Aug 2020'	(b) (4) Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:55:28

US3552140

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:55:28

US3552140

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 19:55:28

US3552140

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	05 Sep 2020 18:21:57

US3552140

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'l'	System	05 Sep 2020 18:21:57

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Joan Siegner (b) (4)	05 Sep 2020 18:22:08

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '05 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:32:56
User entered '5 Sep 2020'	Joan Siegner (b) (4) (b) (4)	05 Sep 2020 18:22:08

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4) [REDACTED]	05 Sep 2020 18:22:08

US3552140

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:22:08

US3552140

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Joan Siegner (b) (4)	14 Sep 2020 15:37:02

US3552140

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'l'	System	14 Sep 2020 15:37:02

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Joan Siegner (b) (4)	14 Sep 2020 15:37:37

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '12 Sep 2020'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 15:37:37

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Joan Siegner (b) (4)	14 Sep 2020 15:37:37

US3552140

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Joan Siegner (b) (4) [REDACTED]	14 Sep 2020 15:37:37

US3552140

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:21:28

US3552140

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'l'	System	21 Sep 2020 16:21:28

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:21:40

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '21 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:21:40

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:21:40

US3552140

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'VISIT2'	System	21 Sep 2020 16:21:40

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '21 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 16:33:45
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 16:33:45
User entered '09:15' reason for change: Data Entry Error	Stanley Dublin (b) (4)	21 Sep 2020 16:33:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 16:33:35
User entered empty.	System	21 Sep 2020 16:33:35
	Stanley Dublin (b) (4)	21 Sep 2020 16:33:35
	(b) (4)	

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '21 Sep 2020 09:15'	System	21 Sep 2020 16:33:45
User entered empty.	System	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '98.1' F	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '100'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'bpm'	System	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '14'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'breaths/min'	System	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '156'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'mmHg'	System	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '81'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'mmHg'	System	21 Sep 2020 16:33:35

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	21 Sep 2020 16:34:52
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	21 Sep 2020 16:34:09
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty; reason for change Data Entry Error	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:24
User entered '21 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty; reason for change Data Entry Error	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:52
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty; reason for change Data Entry Error	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:38
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:34:38
User entered 'bpm'	System	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty; reason for change Data Entry Error	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:38
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:34:38
User entered 'breaths/min'	System	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty; reason for change Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	21 Sep 2020 16:34:38
User entered missing code ND - Not Done.	(b) (4)	
	Stanley Dublin (b) (4)	21 Sep 2020 16:34:09
	(b) (4)	

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:34:38
User entered 'mmHg'	System	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty; reason for change Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	21 Sep 2020 16:34:38
User entered missing code ND - Not Done.	(b) (4)	
	Stanley Dublin (b) (4)	21 Sep 2020 16:34:09
	(b) (4)	

US3552140

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:34:38
User entered 'mmHg'	System	21 Sep 2020 16:34:09

US3552140

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:35:06

US3552140

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:35:06

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Physician Decision (PHYSICIAN DECISION)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'STILL RECOVERING FROM RECENT RETINAL DETACHMENT SURGERY'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:36:33

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	21 Sep 2020 16:37:17
User entered 'No (N)'	(b) (4)	
	Stanley Dublin (b) (4)	21 Sep 2020 16:36:41
	(b) (4)	

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '21 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:37:17
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:36:41

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '09:40' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:37:17
User entered empty.	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:36:41

US3552140

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '21 Sep 2020 09:40'	System	21 Sep 2020 16:37:17
User entered empty.	System	21 Sep 2020 16:36:41

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '21 Sep 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '09:45'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '21 Sep 2020 09:45'	System	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4)	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	21 Sep 2020 16:37:02

US3552140

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 14:59:34

US3552140

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'I'	System	29 Sep 2020 14:59:34

US3552140

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 14:59:49

US3552140

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '28 Sep 2020'	(b) (4) Stanley Dublin (b) (4)	29 Sep 2020 14:59:49

US3552140

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 14:59:49

US3552140

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	29 Sep 2020 14:59:49

US3552140

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 18:08:55

US3552140

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'l'	System	05 Oct 2020 18:08:55

US3552140

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 18:09:04

US3552140

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '05 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:33:15
User entered '5 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 18:09:04

US3552140

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 18:09:04

US3552140

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 18:09:04

US3552140

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 19:49:58

US3552140

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'l'	System	12 Oct 2020 19:49:58

US3552140

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 19:50:06

US3552140

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '12 Oct 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 19:50:06

US3552140

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 19:50:06

US3552140

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 19:50:06

US3552140

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:16:43

US3552140

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'l'	System	16 Oct 2020 20:16:43

US3552140

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:16:53

US3552140

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '16 Oct 2020'	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:16:53

US3552140

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:16:53

US3552140

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'VISIT3'	System	16 Oct 2020 20:16:53

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:53
DataPoint Verified.		12 Nov 2020 14:41:13
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 14:41:55
DataPoint Verified.		12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4)	16 Oct 2020 20:16:58
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	12 Nov 2020 14:41:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4)	16 Oct 2020 20:16:58
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:58
DataPoint Verified.		12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	12 Nov 2020 14:42:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4)	16 Oct 2020 20:16:58
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:02
DataPoint Verified.		12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	12 Nov 2020 14:42:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4)	16 Oct 2020 20:16:58
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:06
DataPoint Verified.		12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	12 Nov 2020 14:42:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4)	16 Oct 2020 20:16:58
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	12 Nov 2020 14:42:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:13
User entered empty.	Mikayla Frye (b) (4)	16 Oct 2020 20:16:58
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered empty.	System	16 Oct 2020 20:16:58

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38

US3552140

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38

US3552140

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:47
DataPoint Verified.		12 Nov 2020 14:41:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:17:04

US3552140

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:49
DataPoint Verified.		12 Nov 2020 14:41:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	16 Oct 2020 20:17:04

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	12 Nov 2020 14:41:38
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:26
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	16 Oct 2020 20:17:15
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	12 Nov 2020 14:41:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:26
User entered '16 Oct 2020'	Mikayla Frye (b) (4)	16 Oct 2020 20:17:15
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Un-verified.	(b) (4)	12 Nov 2020 14:41:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:26
User entered '14:20'	Mikayla Frye (b) (4)	16 Oct 2020 20:17:15
	(b) (4)	

US3552140

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered '16 Oct 2020 14:20'	System	16 Oct 2020 20:17:15

US3552140

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Joan Siegner (b) (4)	12 Nov 2020 15:54:33

US3552140

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'I'	System	12 Nov 2020 15:54:33

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 64'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14
Data entry locked.	System	22 Aug 2020 18:41:13
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:21:14
Data entry locked.	System	22 Aug 2020 18:41:13
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 71'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-10-29T07:15:03', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bcd59382-3ce9-498d-9b35-2e45688bff04'	System	29 Oct 2020 12:16:21
User entered 'No (N)'	System	29 Oct 2020 12:16:21

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-10-29T07:15:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bcd59382-3ce9-498d-9b35-2e45688bff04'	System	29 Oct 2020 12:16:21
User entered 'No (N)'	System	29 Oct 2020 12:16:21

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-10-29T07:16:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bcd59382-3ce9-498d-9b35-2e45688bff04'	System	29 Oct 2020 12:16:21
User entered '29 Oct 2020 07:16:12'	System	29 Oct 2020 12:16:21

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 78'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-05T06:30:06', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f0a8f21e-6578-4e3d-aa54-fla40bba2829'	System	05 Nov 2020 12:31:09
User entered 'No (N)'	System	05 Nov 2020 12:31:09

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-05T06:31:01', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f0a8f21e-6578-4e3d-aa54-fla40bba2829'	System	05 Nov 2020 12:31:09
User entered 'No (N)'	System	05 Nov 2020 12:31:09

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-05T06:31:08', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f0a8f21e-6578-4e3d-aa54-f1a40bba2829' User entered '05 Nov 2020 06:31:08'	System	05 Nov 2020 12:31:09
	System	05 Nov 2020 12:31:09

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered 'Day 92'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-19T07:16:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5d46b94a-46e7-4268-8006-8b9f19f0c2cc'	System	19 Nov 2020 13:16:42
User entered 'No (N)'	System	19 Nov 2020 13:16:42

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-19T07:16:15', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5d46b94a-46e7-4268-8006-8b9f19f0c2cc'	System	19 Nov 2020 13:16:42
User entered 'No (N)'	System	19 Nov 2020 13:16:42

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-19T07:16:39', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5d46b94a-46e7-4268-8006-8b9f19f0c2cc'	System	19 Nov 2020 13:16:42
User entered '19 Nov 2020 07:16:39'	System	19 Nov 2020 13:16:42

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 18:41:13

US3552140

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:58:38
Data entry locked.	System	22 Aug 2020 18:41:13
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 18:41:13

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-26T00:20:29', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '46541af9-af6a-4a9f-b482-15124aca1336'	System	26 Nov 2020 06:20:59
User entered 'No (N)'	System	26 Nov 2020 06:20:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-26T00:20:42', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '46541af9-af6a-4a9f-b482-15124aca1336'	System	26 Nov 2020 06:20:59
User entered 'No (N)'	System	26 Nov 2020 06:20:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-11-26T00:20:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '46541af9-af6a-4a9f-b482-15124aca1336'	System	26 Nov 2020 06:20:59
User entered '26 Nov 2020 00:20:57'	System	26 Nov 2020 06:20:59

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:05:19
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'no AE to be reported' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	08 Mar 2021 22:34:11
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 13:30:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-04T11:45:09', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c03551a4-e68e-474e-9df7-cdff7cd5ae3'	System	04 Dec 2020 17:47:11
User entered 'Yes (Y)'	System	04 Dec 2020 17:47:11

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-04T11:46:22', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c03551a4-e68e-474e-9df7-cdff7cd5ae3'	System	04 Dec 2020 17:47:11
User entered 'No (N)'	System	04 Dec 2020 17:47:11

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2020-12-04T11:46:28', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c03551a4-e68e-474e-9df7-cdff7cd5ae3'	System	04 Dec 2020 17:47:11
User entered 'No (N)'	System	04 Dec 2020 17:47:11

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2020-12-04T11:46:47', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c03551a4-e68e-474e-9df7-cdff7cd5ae3'	System	04 Dec 2020 17:47:11
User entered 'Yes (Y)'	System	04 Dec 2020 17:47:11

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-04T11:46:57', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c03551a4-e68e-474e-9df7-cdff7cd5ae3'	System	04 Dec 2020 17:47:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 17:47:11

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-04T11:47:01', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c03551a4-e68e-474e-9df7-cdff7cd5ae3'	System	04 Dec 2020 17:47:11
User entered '04 Dec 2020 11:47:01'	System	04 Dec 2020 17:47:11

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-07T04:54:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ce78b27-8a44-42a4-8b5f-a6fd785b920c'	System	07 Dec 2020 10:54:39
User entered 'No (N)'	System	07 Dec 2020 10:54:39

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-07T04:54:28', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ce78b27-8a44-42a4-8b5f-a6fd785b920c'	System	07 Dec 2020 10:54:39
User entered 'No (N)'	System	07 Dec 2020 10:54:39

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-07T04:54:35', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '3ce78b27-8a44-42a4-8b5f-a6fd785b920c'	System	07 Dec 2020 10:54:39
User entered '07 Dec 2020 04:54:35'	System	07 Dec 2020 10:54:39

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-15T17:58:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd60ec573-ceba-4d3b-a95d-289c36b4626b'	System	15 Dec 2020 23:59:37
User entered 'No (N)'	System	15 Dec 2020 23:59:37

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-15T17:59:02', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd60ec573-ceba-4d3b-a95d-289c36b4626b'	System	15 Dec 2020 23:59:37
User entered 'No (N)'	System	15 Dec 2020 23:59:37

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-15T17:59:31', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'd60ec573-ceba-4d3b-a95d-289c36b4626b' User entered '15 Dec 2020 17:59:31'	System	15 Dec 2020 23:59:37
	System	15 Dec 2020 23:59:37

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-24T18:00:49', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'ff24ecab-2b0f-4e45-b39a-1b1836c25ef0'	System	25 Dec 2020 00:01:05
User entered 'No (N)'	System	25 Dec 2020 00:01:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-24T18:00:44', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'ff24ecab-2b0f-4e45-b39a-1b1836c25ef0'	System	25 Dec 2020 00:01:05
User entered 'No (N)'	System	25 Dec 2020 00:01:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-24T18:01:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'ff24ecab-2b0f-4e45-b39a-1b1836c25ef0'	System	25 Dec 2020 00:01:05
User entered '24 Dec 2020 18:01:00'	System	25 Dec 2020 00:01:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-28T04:09:18', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2b3c98be-07ed-4c88-b933-0b29ad3b11fb'	System	28 Dec 2020 10:09:56
User entered 'Yes (Y)'	System	28 Dec 2020 10:09:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-28T04:09:25', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2b3c98be-07ed-4c88-b933-0b29ad3b11fb'	System	28 Dec 2020 10:09:56
User entered 'No (N)'	System	28 Dec 2020 10:09:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2020-12-28T04:09:29', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2b3c98be-07ed-4c88-b933-0b29ad3b11fb'	System	28 Dec 2020 10:09:56
User entered 'No (N)'	System	28 Dec 2020 10:09:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2020-12-28T04:09:35', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2b3c98be-07ed-4c88-b933-0b29ad3b11fb'	System	28 Dec 2020 10:09:56
User entered 'Yes (Y)'	System	28 Dec 2020 10:09:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-28T04:09:41', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2b3c98be-07ed-4c88-b933-0b29ad3b11fb'	System	28 Dec 2020 10:09:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Dec 2020 10:09:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2020-12-28T04:09:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '2b3c98be-07ed-4c88-b933-0b29ad3b11fb'	System	28 Dec 2020 10:09:56
User entered '28 Dec 2020 04:09:46'	System	28 Dec 2020 10:09:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-04T05:15:05', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '74623abc-772d-49ec-b099-45de1f2f9522'	System	04 Jan 2021 11:16:05
User entered 'No (N)'	System	04 Jan 2021 11:16:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-04T05:15:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '74623abc-772d-49ec-b099-45de1f2f9522'	System	04 Jan 2021 11:16:05
User entered 'Yes (Y)'	System	04 Jan 2021 11:16:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-04T05:15:31', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '74623abc-772d-49ec-b099-45de1f2f9522'	System	04 Jan 2021 11:16:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 11:16:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-04T05:15:56', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '74623abc-772d-49ee-b099-45de1f2f9522'	System	04 Jan 2021 11:16:05
User entered '04 Jan 2021 05:15:56'	System	04 Jan 2021 11:16:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-11T11:28:56', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '65ef2e0e-d771-44a8-a1dc-9e6bf6aba150'	System	11 Jan 2021 17:29:15
User entered 'No (N)'	System	11 Jan 2021 17:29:15

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-11T11:29:05', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '65ef2e0e-d771-44a8-a1dc-9e6bf6aba150'	System	11 Jan 2021 17:29:15
User entered 'No (N)'	System	11 Jan 2021 17:29:15

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-11T11:29:11', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '65ef2e0e-d771-44a8-a1dc-9e6bf6aba150'	System	11 Jan 2021 17:29:15
User entered '11 Jan 2021 11:29:11'	System	11 Jan 2021 17:29:15

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-18T05:31:44', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'ff1663a9-1e0f-494c-b14d-433d30a55523'	System	18 Jan 2021 11:32:05
User entered 'No (N)'	System	18 Jan 2021 11:32:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-18T05:31:56', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'ff1663a9-1e0f-494c-b14d-433d30a55523'	System	18 Jan 2021 11:32:05
User entered 'No (N)'	System	18 Jan 2021 11:32:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-18T05:32:01', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'ff1663a9-1e0f-494c-b14d-433d30a55523' User entered '18 Jan 2021 05:32:01'	System	18 Jan 2021 11:32:05

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-26T21:29:03', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '880a8b90-6657-41d4-b40c-7c97f94b0155'	System	27 Jan 2021 03:29:40
User entered 'Yes (Y)'	System	27 Jan 2021 03:29:40

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-26T21:29:10', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '880a8b90-6657-41d4-b40c-7c97f94b0155'	System	27 Jan 2021 03:29:40
User entered 'No (N)'	System	27 Jan 2021 03:29:40

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2021-01-26T21:29:15', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '880a8b90-6657-41d4-b40c-7c97f94b0155'	System	27 Jan 2021 03:29:40
User entered 'No (N)'	System	27 Jan 2021 03:29:40

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2021-01-26T21:29:21', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '880a8b90-6657-41d4-b40c-7c97f94b0155'	System	27 Jan 2021 03:29:40
User entered 'Yes (Y)'	System	27 Jan 2021 03:29:40

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-26T21:29:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '880a8b90-6657-41d4-b40c-7c97f94b0155'	System	27 Jan 2021 03:29:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Jan 2021 03:29:40

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-01-26T21:29:27', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '880a8b90-6657-41d4-b40c-7c97f94b0155'	System	27 Jan 2021 03:29:40
User entered '26 Jan 2021 21:29:27'	System	27 Jan 2021 03:29:40

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-01T00:01:35', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '01648391-4667-43c5-94cf-d0f0df14f7b4'	System	01 Feb 2021 06:01:50
User entered 'No (N)'	System	01 Feb 2021 06:01:50

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-01T00:01:41', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '01648391-4667-43c5-94cf-d0f0df14f7b4'	System	01 Feb 2021 06:01:50
User entered 'No (N)'	System	01 Feb 2021 06:01:50

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-01T00:01:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '01648391-4667-43c5-94cf-d0f0df14f7b4'	System	01 Feb 2021 06:01:50
User entered '01 Feb 2021 00:01:46'	System	01 Feb 2021 06:01:50

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-08T12:04:04', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1cc1d7cf-64dc-4e38-8c0d-3e274128581f'	System	08 Feb 2021 18:07:15
User entered 'No (N)'	System	08 Feb 2021 18:07:15

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-08T12:04:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1cc1d7cf-64dc-4e38-8c0d-3e274128581f'	System	08 Feb 2021 18:07:15
User entered 'No (N)'	System	08 Feb 2021 18:07:15

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-08T12:04:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1cc1d7cf-64dc-4e38-8c0d-3e274128581f' User entered '08 Feb 2021 12:04:16'	System	08 Feb 2021 18:07:15

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-15T03:25:13', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '07be23df-9fa3-4649-95e4-6b72c09254a0'	System	15 Feb 2021 09:25:39
User entered 'No (N)'	System	15 Feb 2021 09:25:39

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-15T03:25:24', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '07be23df-9fa3-4649-95e4-6b72c09254a0'	System	15 Feb 2021 09:25:39
User entered 'No (N)'	System	15 Feb 2021 09:25:39

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-15T03:25:35', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '07be23df-9fa3-4649-95e4-6b72c09254a0'	System	15 Feb 2021 09:25:39
User entered '15 Feb 2021 03:25:35'	System	15 Feb 2021 09:25:39

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-22T10:43:13', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'eddc7987-5774-48bf-9a7f-545ceca682dc'	System	22 Feb 2021 16:43:28
User entered 'No (N)'	System	22 Feb 2021 16:43:28

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-22T10:43:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'eddc7987-5774-48bf-9a7f-545ceca682dc'	System	22 Feb 2021 16:43:28
User entered 'No (N)'	System	22 Feb 2021 16:43:28

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-02-22T10:43:23', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'eddc7987-5774-48bf-9a7f-545ceca682dc'	System	22 Feb 2021 16:43:28
User entered '22 Feb 2021 10:43:23'	System	22 Feb 2021 16:43:28

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-01T08:28:26', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f2de1b1e-628b-44f9-bc29-53e03100336f'	System	01 Mar 2021 14:28:41
User entered 'No (N)'	System	01 Mar 2021 14:28:41

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-01T08:28:34', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f2de1b1e-628b-44f9-bc29-53e03100336f'	System	01 Mar 2021 14:28:41
User entered 'No (N)'	System	01 Mar 2021 14:28:41

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-01T08:28:39', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'f2de1b1e-628b-44f9-bc29-53e03100336f' User entered '01 Mar 2021 08:28:39'	System	01 Mar 2021 14:28:41

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-11T20:44:16', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '4f35a85d-86f2-4114-b052-21e8de4e9748'	System	12 Mar 2021 02:44:29
User entered 'No (N)'	System	12 Mar 2021 02:44:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-11T20:44:19', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '4f35a85d-86f2-4114-b052-21e8de4e9748'	System	12 Mar 2021 02:44:29
User entered 'No (N)'	System	12 Mar 2021 02:44:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-11T20:44:26', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '4f35a85d-86f2-4114-b052-21e8de4e9748'	System	12 Mar 2021 02:44:29
User entered '11 Mar 2021 20:44:26'	System	12 Mar 2021 02:44:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-18T06:15:12', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c36253a1-4354-43c0-a4a6-129963cb5f10'	System	18 Mar 2021 11:15:26
User entered 'No (N)'	System	18 Mar 2021 11:15:26

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-18T06:15:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c36253a1-4354-43c0-a4a6-129963cb5f10'	System	18 Mar 2021 11:15:26
User entered 'No (N)'	System	18 Mar 2021 11:15:26

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-18T06:15:22', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'c36253a1-4354-43c0-a4a6-129963cb5f10'	System	18 Mar 2021 11:15:26
User entered '18 Mar 2021 06:15:22'	System	18 Mar 2021 11:15:26

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-22T06:07:36', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '31f40ba2-ca11-40ea-8f57-3b18caaaa984'	System	22 Mar 2021 11:07:56
User entered 'No (N)'	System	22 Mar 2021 11:07:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-22T06:07:48', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '31f40ba2-ca11-40ea-8f57-3b18caaaa984'	System	22 Mar 2021 11:07:56
User entered 'No (N)'	System	22 Mar 2021 11:07:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-22T06:07:53', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '31f40ba2-ca11-40ea-8f57-3b18caaaa984'	System	22 Mar 2021 11:07:56
User entered '22 Mar 2021 06:07:53'	System	22 Mar 2021 11:07:56

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-01T09:58:45', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '0806f1a4-ef34-494e-8f79-7893c87b1822'	System	01 Apr 2021 15:00:29
User entered 'Yes (Y)'	System	01 Apr 2021 15:00:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-01T09:58:54', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '0806f1a4-ef34-494e-8f79-7893c87b1822'	System	01 Apr 2021 15:00:29
User entered 'No (N)'	System	01 Apr 2021 15:00:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2021-04-01T09:59:30', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '0806f1a4-ef34-494e-8f79-7893c87b1822'	System	01 Apr 2021 15:00:29
User entered 'No (N)'	System	01 Apr 2021 15:00:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2021-04-01T09:59:37', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '0806f1a4-ef34-494e-8f79-7893c87b1822'	System	01 Apr 2021 15:00:29
User entered 'Yes (Y)'	System	01 Apr 2021 15:00:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-01T09:59:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '0806f1a4-ef34-494e-8f79-7893c87b1822'	System	01 Apr 2021 15:00:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Apr 2021 15:00:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-01T10:00:14', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '0806f1a4-ef34-494e-8f79-7893c87b1822'	System	01 Apr 2021 15:00:29
User entered '01 Apr 2021 10:00:14'	System	01 Apr 2021 15:00:29

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-07T02:19:19', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '06b616a4-f0ce-42a5-a9f7-747f08c52575'	System	07 Apr 2021 07:19:41
User entered 'No (N)'	System	07 Apr 2021 07:19:41

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-07T02:19:25', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '06b616a4-f0ce-42a5-a9f7-747f08c52575'	System	07 Apr 2021 07:19:41
User entered 'No (N)'	System	07 Apr 2021 07:19:41

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-07T02:19:33', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '06b616a4-f0ce-42a5-a9f7-747f08c52575'	System	07 Apr 2021 07:19:41
User entered '07 Apr 2021 02:19:33'	System	07 Apr 2021 07:19:41

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-13T09:07:17', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1eb24370-71a5-4512-9a61-eee31c3c933c'	System	13 Apr 2021 14:08:08
User entered 'Yes (Y)'	System	13 Apr 2021 14:08:08

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-13T09:07:23', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1eb24370-71a5-4512-9a61-eee31c3c933c'	System	13 Apr 2021 14:08:08
User entered 'No (N)'	System	13 Apr 2021 14:08:08

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2021-04-13T09:07:30', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1eb24370-71a5-4512-9a61-eee31c3c933c'	System	13 Apr 2021 14:08:08
User entered 'No (N)'	System	13 Apr 2021 14:08:08

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2021-04-13T09:07:36', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1eb24370-71a5-4512-9a61-eee31c3c933c'	System	13 Apr 2021 14:08:08
User entered 'Yes (Y)'	System	13 Apr 2021 14:08:08

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-13T09:07:42', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1eb24370-71a5-4512-9a61-eee31c3c933c'	System	13 Apr 2021 14:08:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Apr 2021 14:08:08

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-13T09:07:46', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '1eb24370-71a5-4512-9a61-eee31c3c933c'	System	13 Apr 2021 14:08:08
User entered '13 Apr 2021 09:07:46'	System	13 Apr 2021 14:08:08

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-19T09:54:35-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bd89a111-1508-4ecd-ab70-7aa2f84ac368'	System	19 Apr 2021 14:54:45
User entered 'No (N)'	System	19 Apr 2021 14:54:45

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-19T09:54:38-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bd89a111-1508-4ecd-ab70-7aa2f84ac368'	System	19 Apr 2021 14:54:45
User entered 'No (N)'	System	19 Apr 2021 14:54:45

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-19T09:54:41-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'bd89a111-1508-4ecd-ab70-7aa2f84ac368'	System	19 Apr 2021 14:54:45
User entered '19 Apr 2021 09:54:41'	System	19 Apr 2021 14:54:45

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-30T14:30:14-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5ed858e3-b256-4071-a812-17c75b3e6363'	System	30 Apr 2021 19:31:02
User entered 'Yes (Y)'	System	30 Apr 2021 19:31:02

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-30T14:30:23-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5ed858e3-b256-4071-a812-17c75b3e6363'	System	30 Apr 2021 19:31:02
User entered 'No (N)'	System	30 Apr 2021 19:31:02

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2021-04-30T14:30:31-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5ed858e3-b256-4071-a812-17c75b3e6363'	System	30 Apr 2021 19:31:02
User entered 'No (N)'	System	30 Apr 2021 19:31:02

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[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 (e1d2cd685b0a0b02)', Time: '2021-04-30T14:30:37-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5ed858e3-b256-4071-a812-17c75b3e6363'	System	30 Apr 2021 19:31:02
User entered 'Yes (Y)'	System	30 Apr 2021 19:31:02

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-30T14:30:46-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5ed858e3-b256-4071-a812-17c75b3e6363'	System	30 Apr 2021 19:31:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Apr 2021 19:31:02

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-04-30T14:30:50-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '5ed858e3-b256-4071-a812-17c75b3e6363'	System	30 Apr 2021 19:31:02
User entered '30 Apr 2021 14:30:50'	System	30 Apr 2021 19:31:02

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-05-03T09:16:34-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '56bf67db-f242-40bd-9456-ef3cdf921616'	System	03 May 2021 14:16:48
User entered 'No (N)'	System	03 May 2021 14:16:48

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-05-03T09:16:38-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '56bf67db-f242-40bd-9456-ef3cdf921616'	System	03 May 2021 14:16:48
User entered 'No (N)'	System	03 May 2021 14:16:48

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-05-03T09:16:43-05:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: '56bf67db-f242-40bd-9456-ef3cdf921616'	System	03 May 2021 14:16:48
User entered '03 May 2021 09:16:43'	System	03 May 2021 14:16:48

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:21:14

US3552140

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:09:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:21:14
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:21:14

US3552140

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:09:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-01T08:28:51', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'ba8d4af3-cea2-4b9a-99d6-19c638c6fe69'	System	01 Mar 2021 14:29:03
User entered 'No (N)'	System	01 Mar 2021 14:29:03

US3552140

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:09:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e1d2cd685b0a0b02)', Time: '2021-03-01T08:29:00', User OID: 'PatientReportedOutcome (US3552140)', ODM File OID: 'ba8d4af3-cea2-4b9a-99d6-19c638c6fe69'	System	01 Mar 2021 14:29:03
User entered '01 Mar 2021 08:29:00'	System	01 Mar 2021 14:29:03

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Joan Siegner (b) (4)	12 Nov 2020 15:54:46

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered '18 Nov 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	19 Nov 2020 15:10:36
User entered '12 Nov 2020'	Joan Siegner (b) (4) (b) (4)	12 Nov 2020 15:54:46

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	Joan Siegner (b) (4) [REDACTED]	12 Nov 2020 15:54:46

US3552140

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered empty.	Joan Siegner (b) (4)	12 Nov 2020 15:54:46

US3552140

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	17 Dec 2020 16:30:41

US3552140

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:52:38
User entered 'l'	System	17 Dec 2020 16:30:41

US3552140

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Dec 2020 16:30:52

US3552140

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '17 Dec 2020'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Dec 2020 16:30:52

US3552140

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	17 Dec 2020 16:30:52

US3552140

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Dec 2020 16:30:52

US3552140

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Jan 2021 17:06:49

US3552140

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered 'l'	System	19 Jan 2021 17:06:49

US3552140

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Jan 2021 17:06:58

US3552140

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '19 Jan 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Jan 2021 17:06:58

US3552140

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Jan 2021 17:06:58

US3552140

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Jan 2021 17:06:58

US3552140

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 16:03:10

US3552140

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered 'I'	System	17 Feb 2021 16:03:10

US3552140

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 16:03:20

US3552140

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '16 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 16:03:20

US3552140

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 16:03:20

US3552140

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	17 Feb 2021 16:03:20

US3552140

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	17 Feb 2021 20:11:31

US3552140

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered 'l'	System	17 Feb 2021 20:11:31

US3552140

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:07

US3552140

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered '23 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:07

US3552140

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:07

US3552140

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered 'VISIT4'	System	24 Mar 2021 12:13:07

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:22:48
User entered 'No (N)'	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:22:48
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:22:48
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered empty.	System	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:22:48
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:22:48
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:22:48
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:22:48
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered empty.	System	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:22:48
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered empty.	System	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4) (b) (4)	30 Mar 2021 16:22:48
User entered empty.	Cassandra Zehenny (b) (4) (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered empty.	System	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	30 Mar 2021 16:22:48
User entered empty.	(b) (4) Cassandra Zehenny (b) (4)	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered empty.	System	29 Mar 2021 20:17:45

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28

US3552140

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28

US3552140

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:10

US3552140

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:10

US3552140

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:20

US3552140

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered '23 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:20

US3552140

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered '13:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:20

US3552140

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered '23 Mar 2021 13:45'	System	24 Mar 2021 12:13:20

US3552140

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:13:23

US3552140

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:48:28
User entered 'l'	System	24 Mar 2021 12:13:23

US3552140

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:39:11
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 15:05:11

US3552140

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:39:11
User entered '19 Apr 2021'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 15:05:11

US3552140

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:39:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 15:05:11

US3552140

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:39:11
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	19 Apr 2021 15:05:11

US3552140

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	20 Apr 2021 19:39:11
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	19 Apr 2021 15:05:14

US3552140

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 15:05:14

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:28:57

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	01 Feb 2021 17:29:05
User entered '1 Feb 2021'	(b) (4)	
	Stanley Dublin (b) (4)	01 Feb 2021 17:28:57
	(b) (4)	

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Clinic (Clinic)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:28:57

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 17:28:57

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:45
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:21:32

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	23 Mar 2021 15:26:45
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:21:32

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Placebo (Placebo)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Not Administered (NA)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'I'	System	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:09:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'I'	System	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered empty.	System	01 Feb 2021 17:39:33
DataPoint set to visible.	System	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered empty.	System	01 Feb 2021 17:39:33
DataPoint set to visible.	System	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '10:05'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '01 Feb 2021 10:05'	System	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '97.1' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '88'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'bpm'	System	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '12'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'breaths/min'	System	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '124'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mmHg'	System	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '82'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mmHg'	System	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered missing code ND - Not Done.	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:39:33

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:09:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered empty.	System	01 Feb 2021 17:39:33
DataPoint set to visible.	System	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '11:09'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '01 Feb 2021 11:09'	System	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '97.3' F	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '88'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'bpm'	System	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '12'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'breaths/min'	System	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '122'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mmHg'	System	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '80'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mmHg'	System	01 Feb 2021 17:40:12

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:28

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:28

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Doublin (b) (4) (b) (4)	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mRNA-1273'	System	01 Feb 2021 17:40:43
DataPoint set to visible.	System	01 Feb 2021 17:39:02

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '10:39'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '01 Feb 2021 10:39'	System	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'ONCE'	System	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 17:40:43

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:58

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:58

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '09:48'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:40:58

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '01 Feb 2021 09:48'	System	01 Feb 2021 17:40:58

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4)	01 Feb 2021 17:41:08

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '01 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:41:08

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '09:51'	(b) (4) Stanley Dublin (b) (4) (b) (4)	01 Feb 2021 17:41:08

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:09:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '01 Feb 2021 09:51'	System	01 Feb 2021 17:41:08

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 19:27:22

US3552140

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'I'	System	08 Feb 2021 19:27:22

US3552140

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 19:27:39

US3552140

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '08 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 19:27:39

US3552140

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 19:27:39

US3552140

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	08 Feb 2021 19:27:39

US3552140

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	17 Feb 2021 20:11:36

US3552140

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'l'	System	17 Feb 2021 20:11:36

US3552140

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'I'	System	17 Feb 2021 20:11:36
DataPoint set to visible.	System	17 Feb 2021 20:11:36

US3552140

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:13

US3552140

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:13

US3552140

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:13

US3552140

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'OLD29'	System	26 Feb 2021 17:05:13

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '09:44'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '26 Feb 2021 09:44'	System	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '98.9' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '101'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'bpm'	System	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '14'	(b) (4) Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'breaths/min'	System	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '137'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mmHg'	System	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '82'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mmHg'	System	26 Feb 2021 17:05:36

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '10:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '26 Feb 2021 10:45'	System	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '97.4' F	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Oral (Oral)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '90'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'bpm'	System	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '14'	(b) (4) Stanley Doublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'breaths/min'	System	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '138'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mmHg'	System	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '87'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mmHg'	System	26 Feb 2021 17:07:20

US3552140

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:33

US3552140

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:07:33

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:09:02

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:09:02

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:09:02

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'mRNA-1273'	System	26 Feb 2021 17:09:02
DataPoint set to visible.	System	17 Feb 2021 20:11:36

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '26 Feb 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:09:02

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered '10:15' reason for change: Data Entry Error	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 17:09:15
User entered '10:45'	(b) (4)	
	Stanley Dublin (b) (4)	26 Feb 2021 17:09:02
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '26 Feb 2021 10:15'	System	26 Feb 2021 17:09:15
User entered '26 Feb 2021 10:45'	System	26 Feb 2021 17:09:02

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:09:02

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'ONCE'	System	26 Feb 2021 17:09:02

US3552140

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:09:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 17:09:02

US3552140

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	27 Feb 2021 17:54:11
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	26 Feb 2021 17:37:04

US3552140

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'l'	System	26 Feb 2021 17:37:04

US3552140

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:54:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 16:07:21

US3552140

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:54:53
User entered '5 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 16:07:21

US3552140

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:54:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 16:07:21

US3552140

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:09:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:54:53
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 16:07:21

US3552140

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	09 Mar 2021 16:54:53
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	05 Mar 2021 16:07:27

US3552140

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:09:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'l'	System	05 Mar 2021 16:07:27

US3552140

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:40

US3552140

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered '23 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:40

US3552140

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'Clinic (Clinic)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:40

US3552140

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:09:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered 'OLD57'	System	24 Mar 2021 12:12:40

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered empty.	System	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered empty.	System	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Doublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered empty.	System	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered empty.	System	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered empty.	System	24 Mar 2021 12:12:45

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07

US3552140

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:09:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07

US3552140

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'No (N)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:48

US3552140

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:09:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered empty.	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:48

US3552140

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered 'Yes (Y)'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:58

US3552140

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered '23 Mar 2021'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:58

US3552140

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User signature succeeded.	sharon frey (b) (4)	29 Mar 2021 13:56:21
User entered '13:45'	(b) (4) Stanley Dublin (b) (4) (b) (4)	24 Mar 2021 12:12:58

US3552140

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:09:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:07
User entered '23 Mar 2021 13:45'	System	24 Mar 2021 12:12:58

US3552140

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:09:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:20
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).		30 Mar 2021 12:38:06
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'please see con procedure #4' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 29 Mar 2021 16:24:28
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 06:35:25
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 15:47:32
User closed query 'Please change response to "yes" - SAE is reported . ' (Site from CRA).		23 Sep 2020 13:59:16

US3552140

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:09:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Please change response to "yes" - SAE is reported . ' answered with 'done' (Site from CRA).	Joan Siegner (b) (4)	19 Sep 2020 12:02:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	19 Sep 2020 12:02:25
User opened query 'Please change response to "yes" - SAE is reported . ' (Site from CRA).	(b) (4), (b) (6)	16 Sep 2020 18:50:04
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	10 Sep 2020 15:10:59
User entered 'Yes (Y)'	Joan Siegner (b) (4)	05 Sep 2020 19:56:30

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:05
Reviewed for Safety.		11 Sep 2020 13:54:36
User entered	System	11 Sep 2020 13:53:03
'USA-US089-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	11 Sep 2020 13:53:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:07
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal detachment, LLT: Retinal detachment - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 11:27:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 11:27:35
Data point term sent to Coder	System	12 Sep 2020 15:22:58
User entered 'Retinal detachment of left eye' reason for change: New Information	Heather Douds (b) (4)	12 Sep 2020 15:22:34
Data point term sent to Coder	System	10 Sep 2020 15:37:28
User entered 'Vision changes'	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:08
User entered 'Yes (Y)'	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:10
User entered 'No (N)'	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:11
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:37:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 15:37:08
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	10 Sep 2020 15:37:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:36:52
User entered empty.	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 14:45:46
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:38
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:33:15
	(b) (4)	
User entered '8 Sep 2020'	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:16
User entered empty.	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:18
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	17 Sep 2020 20:19:01
User entered 'Yes (Y)'	(b) (4)	
	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:20
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Sep 2020 20:19:01
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	17 Sep 2020 20:19:01
User entered '12 Sep 2020' reason for change: New Information	Heather Douds (b) (4)	17 Sep 2020 20:19:01
	(b) (4)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Sep 2020 20:18:38
User entered empty.	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:21
User entered empty.	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 15:41:06
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		16 Sep 2020 18:39:27
User entered empty.	System	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:33:23
User entered 'Grade 3/Severe (Grade 3/Severe)'		10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:27
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:29
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:30
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:32
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:34
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:33:35
User entered empty.		10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:37
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:33:38
User entered '0'		10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:39
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:33:41
User entered 'l'		10 Sep 2020 15:36:52

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:43
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		18 Sep 2020 15:40:33
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'done' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:19:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	17 Sep 2020 20:18:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 20:18:38
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Heather Douds (b) (4)	17 Sep 2020 20:18:38
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 13:48:19
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:36:52
User entered empty.	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:45
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 20:18:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 20:18:38
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Heather Douds (b) (4)	17 Sep 2020 20:18:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:36:52
User entered empty.	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

US3552140

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	04 Nov 2020 15:56:05
User closed query 'Per CDM: Reason for Dosing discontinuation is AE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:40:19
Query 'Per CDM: Reason for Dosing discontinuation is AE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' answered with 'updated' (Site from DM).	Heather Douds (b) (4)	29 Oct 2020 15:23:16
DataPoint Un-verified.	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Heather Douds (b) (4)	29 Oct 2020 15:23:04
User opened query 'Per CDM: Reason for Dosing discontinuation is AE on the Dosing discontinuation form, however the Action with Investigational product is not Investigational product withdrawn. Please reconcile and update data accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 09:30:00
DataPoint Verified.		14 Oct 2020 20:33:47
User closed query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of retinal detachment of left eye.' (Site from Safety).		18 Sep 2020 15:40:37
Query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of retinal detachment of left eye.' answered with 'done' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:19:15
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 20:18:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 20:18:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)' reason for change: New Information	(b) (4), (b) (6)	17 Sep 2020 20:18:38
User opened query 'PV Query: Please provide action taken with study drug, along with dechallenge and rechallenge for event of retinal detachment of left eye.' (Site from Safety).		16 Sep 2020 18:39:43
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 15:36:52
User entered empty.	Heather Douds (b) (4) (b) (4)	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:49
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).		12 Sep 2020 15:22:34
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Sep 2020 15:36:52
User entered '0'	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:33:51
User closed query 'PV Query: It was reported that the subject started three new medications. Please provide the medications and any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety). Query 'PV Query: It was reported that the subject started three new medications. Please provide the medications and any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'added to con meds' (Site from Safety).	(b) (4), (b) (6)	8 Sep 2020 15:40:41
User entered '1' reason for change: New Information	Heather Douds (b) (4)	17 Sep 2020 20:19:26
User opened query 'PV Query: It was reported that the subject started three new medications. Please provide the medications and any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety). User entered '0'	(b) (4), (b) (6)	16 Sep 2020 18:40:18
	Heather Douds (b) (4)	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:52
User closed query 'PV Query: Noted the subject had surgical correction - please specify what surgery was performed.' (Site from Safety).		18 Sep 2020 15:40:48
Query 'PV Query: Noted the subject had surgical correction - please specify what surgery was performed.' answered with 'done' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:20:28
User opened query 'PV Query: Noted the subject had surgical correction - please specify what surgery was performed.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:40:01
User entered '1' reason for change: New Information	Heather Douds (b) (4)	12 Sep 2020 15:22:34
User entered '0'	Heather Douds (b) (4)	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:56
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		18 Sep 2020 15:40:55
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'done' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:20:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Heather Douds (b) (4)	17 Sep 2020 20:18:38
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:39:13
User entered 'Unknown (UNKNOWN)'	Heather Douds (b) (4)	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:33:58
User entered empty.	Heather Douds (b) (4)	10 Sep 2020 15:36:52
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:34:00
User closed query 'PV Query: Please provide any relevant diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 15:41:50
User closed query 'PV Query: Please confirm the start date of the reported medical history "hypertension" and consider removing the duplicate entry.' (Site from Safety).		18 Sep 2020 15:41:46
User closed query 'PV Query: Please provide ophthalmologist report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.if available.' (Site from Safety).		18 Sep 2020 15:41:43
User closed query 'PV Query: Please report if the subject had any risk factors (i.e glaucoma, family history, myopia, cataract removal, eye injury, etc)' (Site from Safety).		18 Sep 2020 15:41:31
User closed query 'PV Query: This patient saw an OPH for the treatment of the retinal detachment. What was the suspected cause of the retinal detachment?' (Site from Safety).		18 Sep 2020 15:41:25
Query 'PV Query: Please provide ophthalmologist report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.if available.' answered with 'done' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:48:59
Query 'PV Query: This patient saw an OPH for the treatment of the retinal detachment. What was the suspected cause of the retinal detachment?' answered with 'no suspected cause listed in medical records' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:27:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please report if the subject had any risk factors (i.e glaucoma, family history, myopia, cataract removal, eye injury, etc)' answered with 'history of autoimmune disease, unknown family history' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:27:06
User entered 'CONTACTED SUBJECT VIA PHONE AT 9:49 ON 9/10/2020 TO FOLLOW UP ON NEW MEDICATION; SUBJECT SHARED THAT SHE WAS CURRENTLY EXPERIENCING NEW VISION CHANGES/PARTIAL VISION LOSS IN HER LEFT EYE. SHE HAD ALREADY CONTACTED HER OPHTHALMOLOGIST AND WAS WAITING FOR A RETURN CALL. SEEN BY OPHTHALMOLOGIST 9/10, DIAGNOSED WITH RETINAL DETACHMENT OF LEFT EYE, SURGICALLY CORRECTED ON 9/11. THREE NEW MEDICATIONS STARTED, WILL UPDATE CON MEDS WHEN NAMES ARE AVAILABLE. RECORDS NOT YET AVAILABLE TO SITE, WILL SEND WHEN WE HAVE RECEIVED THEM.	Heather Douds (b) (4)	17 Sep 2020 20:25:07
Will fax this afternoon, no lab tests performed. Subject has history of autoimmune disease, unknown if there is family history. No suspected cause listed in medical records.' reason for change: New Information		
Query 'PV Query: Please provide any relevant diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no lab tests' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:22:18
Query 'PV Query: Please confirm the start date of the reported medical history "hypertension" and consider removing the duplicate entry.' answered with 'done' (Site from Safety).	Heather Douds (b) (4)	17 Sep 2020 20:20:41
User opened query 'PV Query: This patient saw an OPH for the treatment of the retinal detachment. What was the suspected cause of the retinal detachment?' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 20:01:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please report if the subject had any risk factors (i.e glaucoma, family history, myopia, cataract removal, eye injury, etc)' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 18:41:22
User opened query 'PV Query: Please provide any relevant diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		16 Sep 2020 18:41:02
User opened query 'PV Query: Please provide ophthalmologist report with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.if available.' (Site from Safety).		16 Sep 2020 18:40:48
User opened query 'PV Query: Please confirm the start date of the reported medical history "hypertension" and consider removing the duplicate entry.' (Site from Safety).		16 Sep 2020 18:40:38
User entered 'CONTACTED SUBJECT VIA PHONE AT 9:49 ON 9/10/2020 TO FOLLOW UP ON NEW MEDICATION; SUBJECT SHARED THAT SHE WAS CURRENTLY EXPERIENCING NEW VISION CHANGES/PARTIAL VISION LOSS IN HER LEFT EYE. SHE HAD ALREADY CONTACTED HER OPHTHALMOLOGIST AND WAS WAITING FOR A RETURN CALL. Seen by ophthalmologist 9/10, diagnosed with retinal detachment of left eye, surgically corrected on 9/11. Three new medications started, will update con meds when names are available. Records not yet available to site, will send when we have received them.' reason for change: New Information	Heather Douds (b) (4) (b) (4)	12 Sep 2020 15:22:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
User entered 'CONTACTED SUBJECT VIA PHONE AT 9:49 on 9/10/2020 TO FOLLOW UP ON NEW MEDICATION; SUBJECT SHARED THAT SHE WAS CURRENTLY EXPERIENCING NEW VISION CHANGES/PARTIAL VISION LOSS IN HER LEFT EYE. SHE HAD ALREADY CONTACTED HER OPHTHALMOLOGIST AND WAS WAITING FOR A RETURN CALL. WILL FOLLOW UP WITH SUBJECT AND GET RECORDS.' reason for change: Data Entry Error	Heather Douds (b) (4)	10 Sep 2020 15:38:16
User entered 'Contacted subject via phone at 9:49 this AM to follow up on new medication; subject shared that she was currently experiencing new vision changes/partial vision loss in her left eye. She had already contacted her ophthalmologist and was waiting for a return call. Will follow up with subject and get records.'	Heather Douds (b) (4)	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:09:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Sep 2020 15:36:52

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:13
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:27:42
Un-reviewed for Safety.		19 Oct 2020 15:28:55
Reviewed for Safety.		05 Oct 2020 12:57:03
User entered 'USA-US089-2020-mRNA-1273-P301000007'	System	05 Oct 2020 12:56:51
User entered 'New'	(b) (4), (b) (6)	05 Oct 2020 12:56:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal tear, LLT: Horseshoe tear of retina without detachment - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 15:13:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Mar 2021 15:13:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User closed query 'PV Query: It was reported the tears were on bilateral retinas. Please confirm if the horseshoe tear occurred in both eyes? Please consider updating the event term, if applicable' (Site from Safety).		28 Oct 2020 15:27:42
Query 'PV Query: It was reported the tears were on bilateral retinas. Please confirm if the horseshoe tear occurred in both eyes? Please consider updating the event term, if applicable' answered with 'Horseshoe tear of right eye. retinal detachment of left eye' (Site from Safety).		27 Oct 2020 19:25:35
User opened query 'PV Query: It was reported the tears were on bilateral retinas. Please confirm if the horseshoe tear occurred in both eyes? Please consider updating the event term, if applicable' (Site from Safety).		26 Oct 2020 16:51:41
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal tear, LLT: Retinal tear - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 16:28:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Oct 2020 07:08:46
Data point term sent to Coder	System	03 Oct 2020 07:08:46
User entered 'Horseshoe tear of right eye'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:59
	(b) (4)	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered 'No (N)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered 'No (N)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 14:46:02
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:55
	(b) (4)	
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User closed query 'Please verify start and end dates. Procedures related to this condition were done on 06Oct and 09Oct .' (Site from CRA).		18 Oct 2020 02:16:25
Query 'Please verify start and end dates. Procedures related to this condition were done on 06Oct and 09Oct .' answered with 'Procedures were done 01Oct and 06Oct. 09Oct was a follow up appointment with her eye doctor- no procedures done on this date. Thank you.' (Site from CRA).	Cassandra Zehenny (b) (4)	15 Oct 2020 15:22:27
	(b) (4)	
User opened query 'Please verify start and end dates. Procedures related to this condition were done on 06Oct and 09Oct .' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 21:00:52
User entered '1 Oct 2020'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered 'No (N)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:28
User closed query 'Please consider updating end date, procedure date for condition is done on 06Oct, per source. Thank you! ' (Site from CRA).		28 Oct 2020 15:50:26
Query 'Please consider updating end date, procedure date for condition is done on 06Oct, per source. Thank you! ' answered with 'updated, thank you' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 15:28:23
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	28 Oct 2020 15:28:17
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	28 Oct 2020 15:28:17
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User opened query 'Please consider updating end date, procedure date for condition is done on 06Oct, per source. Thank you! ' (Site from CRA).		28 Oct 2020 15:27:25
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:17:12
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	02 Oct 2020 19:17:12
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:17:12
User entered '1 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	02 Oct 2020 19:17:12
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:16:45
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	02 Oct 2020 19:16:45
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered 'Grade 3/Severe (Grade 3/Severe)'	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered '0'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered '0'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered '0'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	13 Nov 2020 18:11:51
User closed query 'Subject was formally admitted for same day surgery on 06Oct. Please consider updating the entry. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 18:11:40
Query 'Subject was formally admitted for same day surgery on 06Oct. Please consider updating the entry. ' answered with 'Subject was not admitted, outpatient surgery performed at the hospital. No admission date required.' (Site from CRA).	Heather Douds (b) (4)	13 Nov 2020 16:10:29
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 15:04:29
User opened query 'Subject was formally admitted for same day surgery on 06Oct. Please consider updating the entry. ' (Site from CRA).		13 Nov 2020 15:04:15
DataPoint Verified.		28 Oct 2020 15:27:42
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	13 Nov 2020 18:11:52
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 15:04:27
DataPoint Verified.		28 Oct 2020 15:27:42
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered '0' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Oct 2020 20:43:31
	(b) (4)	
User entered '1'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered '0'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Oct 2020 20:43:31
	(b) (4)	
User entered '0'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 14:11:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 14:11:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	03 Oct 2020 14:11:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Oct 2020 19:16:45
	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 14:11:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 14:11:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	03 Oct 2020 14:11:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:16:45
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 16:23:16
User closed query 'Please update to Not Applicable. Event started and ended after decision was made not to administer the second dose. ' (Site from CRA).		23 Nov 2020 16:23:15
Query 'Please update to Not Applicable. Event started and ended after decision was made not to administer the second dose. ' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	23 Nov 2020 15:35:29
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	23 Nov 2020 15:35:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4)	
	Cassandra Zehenny (b) (4)	23 Nov 2020 15:35:19
User opened query 'Please update to Not Applicable. Event started and ended after decision was made not to administer the second dose. ' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 16:31:37
DataPoint Verified.		28 Oct 2020 15:27:42
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 14:11:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 14:11:31
User entered 'None (NONE)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	03 Oct 2020 14:11:31
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:16:45
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:19:10
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		15 Jan 2021 20:56:02
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	15 Jan 2021 20:56:02
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	15 Jan 2021 20:55:43
DataPoint Un-verified.		
	Cassandra Zehenny (b) (4)	15 Jan 2021 20:55:43
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	15 Jan 2021 20:55:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered '0'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:19:12
User closed query 'Per DM CLR - RQ: Site's response noted. However, CM indication is CRYOTHERAPY OF RIGHT EYE . Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).		18 Jan 2021 11:46:41
Query 'Per DM CLR - RQ: Site's response noted. However, CM indication is CRYOTHERAPY OF RIGHT EYE . Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	15 Jan 2021 20:56:10
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	15 Jan 2021 20:55:43
User entered '0' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	15 Jan 2021 20:55:43
	(b) (4)	
User opened query 'Per DM CLR - RQ: Site's response noted. However, CM indication is CRYOTHERAPY OF RIGHT EYE . Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:37:14
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)	16 Dec 2020 03:30:37
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 'con med 16, 17, 18' (Site from DM).	Cassandra Zehenny (b) (4)	14 Dec 2020 16:26:14

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	12 Dec 2020 06:35:34
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered 'l'	Cassandra Zehenny (b) (4) (b) (4)	(b) (4) 02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered 'l'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User closed query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you' (Site from Safety).		13 Oct 2020 16:45:20
Query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you' answered with 'Unrelated' (Site from Safety).	Cassandra Zehenny (b) (4)	12 Oct 2020 20:22:13
User opened query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:40:45
Query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you, (b) (6)' canceled (Site from Safety).		12 Oct 2020 15:40:20
User opened query 'PV query: Please clarify if the horse shoe retinal tear was a sequela of retinal detachment. Thank you, (b) (6)' (Site from Safety).		12 Oct 2020 15:39:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:27:42
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 28 Oct 2020 15:27:42
User closed query 'PV Query: Please provide start date for concomitant medication of hydrochlorothiazide' (Site from Safety).		27 Oct 2020 19:26:00
Query 'PV Query: Please provide start date for concomitant medication of hydrochlorothiazide' answered with 'Date unknown' (Site from Safety).		26 Oct 2020 16:58:37
User opened query 'PV Query: Please provide start date for concomitant medication of hydrochlorothiazide' (Site from Safety).		22 Oct 2020 16:28:10
User closed query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you' (Site from Safety).		13 Oct 2020 16:45:24
Query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you' answered with 'Corneal lintacs from research study still in place, tears were on bilateral retinas' (Site from Safety).	Cassandra Zehenny (b) (4)	12 Oct 2020 20:22:43
User opened query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:40:52
Query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you, (b) (6)' canceled (Site from Safety).		12 Oct 2020 15:40:26
User opened query 'PV query: Please clarify medical history which states" bilateral corneal intacs". Thank you, (b) (6)' (Site from Safety).		12 Oct 2020 15:39:45
User entered 'Subject reported receiving Laser Eye Treatment to fix a Horseshoe Tear of right eye. States she was at her eye doctor for an appointment about her dry eyes and upon exam they found the tear and wanted to fix it. No complications post-procedure. Has taken ibuprofen x2 since procedure for eye pain which has since resolved.'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	02 Oct 2020 19:16:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 17:06:03

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Folder: Adverse Events

Form: Adverse Events (4)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia worsened - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 15:57:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 15:57:44
Data point term sent to Coder	System	07 Dec 2020 15:56:39
User entered 'fibromyalgia exacerbation'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'No (N)'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'No (N)'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '26 Nov 2020'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User entered empty.	System	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	04 Jan 2021 15:05:15
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '04 Jan 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4)	04 Jan 2021 15:05:15
User entered empty.	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User entered empty.	System	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
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	07 Dec 2020 16:23:20
User entered 'No (N)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	07 Dec 2020 16:23:20
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	07 Dec 2020 15:56:11
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '0'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '0'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '0'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered empty.	Stanley Dublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered empty.	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered empty.	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered empty.	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '0'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '0'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '0'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'Not Related (NOT RELATED)'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'Not Applicable (NOT APPLICABLE)'	Stanley Dublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '0'	Stanley Dublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'l'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered '0'	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	04 Jan 2021 15:05:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stanley Dublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:35
User entered empty.	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:20:35
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 16:23:20
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 16:23:20
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	07 Dec 2020 15:56:11
User entered empty.	Stanley Doublin (b) (4)	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User entered '0'	System	07 Dec 2020 16:23:20
User entered '1'	System	07 Dec 2020 15:56:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:03
User entered 'I'	System	07 Dec 2020 15:56:11

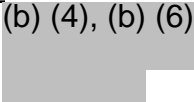
US3552140

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:09:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) 	27 Apr 2021 17:06:03

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 17:06:10

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 17:46:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 17:46:20
Data point term sent to Coder	System	29 Dec 2020 17:45:30
User entered 'lower back pain'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:20:38
User entered 'No (N)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:20:38
User entered 'No (N)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:20:38
User entered '24 Dec 2020'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User entered empty.	System	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'No (N)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	04 Jan 2021 15:05:32
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '04 Jan 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4)	04 Jan 2021 15:05:32
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User entered empty.	System	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'No (N)'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'Not Related (NOT RELATED)'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'Not Applicable (NOT APPLICABLE)'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'l'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	04 Jan 2021 15:05:32
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:20:38
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:20:38
User entered empty.	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:44:42
	(b) (4)	

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User entered '0'	System	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:10
User entered 'I'	System	29 Dec 2020 17:44:42

US3552140

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:09:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 17:06:10

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 17:06:17

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 14:45:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 14:45:46
Data point term sent to Coder	System	13 Apr 2021 14:32:53
User entered 'Fall'	Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '11 Apr 2021'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User entered empty.	System	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '11 Apr 2021'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User entered empty.	System	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4)	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User entered '0'	System	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:06:17
User entered 'I'	System	13 Apr 2021 14:32:36

US3552140

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:09:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 17:06:17

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Abrasion - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Apr 2021 09:41:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:41:54
Data point term sent to Coder	System	13 Apr 2021 14:34:04
User entered 'abrasion to R brow bone'	Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '11 Apr 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 14:33:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Not Related (NOT RELATED)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

None

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 14:33:18

US3552140

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:09:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 14:33:18

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:09:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:20
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:55:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:26:30

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Query 'Please verify if following have been taken by subject. Medication is listed as active in PCP notes. Cevimeline (Evoxac) 30mg X 3, cylcobenzaprine (Flexeril) 10mg X 3 oral as needed, hydrocodone-acetaminophen (Narco) 25mg 7.5-325 mg oral as needed, losartan 100mg once daily, oral hydrochlorthiazide 25mg once daily oral, Savella 100mg X2 daily oral. Thank you ! ' canceled (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 18:26:50
User opened query 'Please verify if following have been taken by subject. Medication is listed as active in PCP notes. Cevimeline (Evoxac) 30mg X 3, cylcobenzaprine (Flexeril) 10mg X 3 oral as needed, hydrocodone-acetaminophen (Narco) 25mg 7.5-325 mg oral as needed, losartan 100mg once daily, oral hydrochlorthiazide 25mg once daily oral, Savella 100mg X2 daily oral. Thank you ! ' (Site from CRA). DataPoint Verified.		13 Nov 2020 18:26:32
		28 Oct 2020 15:50:13
User closed query 'Per PCP notes page 12 subject to continue taking Restasis, Hydroduril and other meds. Please verify if subject is actually taking these meds and update conmed eCRF as needed. Thank you! ' (Site from CRA).		24 Oct 2020 23:19:18
Query 'Per PCP notes page 12 subject to continue taking Restasis, Hydroduril and other meds. Please verify if subject is actually taking these meds and update conmed eCRF as needed. Thank you! ' answered with 'Spoke with subject regarding these medications and confirmed her current med list. Con Med sheet is correct as entered. Thank you!' (Site from CRA).	Cassandra Zehenny (b) (4)	15 Oct 2020 15:21:31
User opened query 'Per PCP notes page 12 subject to continue taking Restasis, Hydroduril and other meds. Please verify if subject is actually taking these meds and update conmed eCRF as needed. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 01:59:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

Name of Medication

Audit	User	Time (GMT)
Query 'Please update list as needed , per PCP notes page 12 subject to continue taking Restasis, Hydrodiuril and other meds. Please verify if subject is actually taking these meds and they have to be added. ' canceled (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 01:58:31
User opened query 'Please update list as needed , per PCP notes page 12 subject to continue taking Restasis, Hydrodiuril and other meds. Please verify if subject is actually taking these meds and they have to be added. ' (Site from CRA).		14 Oct 2020 20:26:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:51:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:51:33
Data point term sent to Coder	System	24 Aug 2020 12:30:57
User entered 'celebrex'	Stanley Doublin (b) (4) (b) (4)	24 Aug 2020 12:30:50

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'rheumatoid'	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '100'	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Stanley Doublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'twice daily (BID)'	Stanley Doublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2015'	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:30:50

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:30:50
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 12:30:50

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	24 Aug 2020 12:30:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 12:30:50

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE, PRODUCTSYNONYM: BUMEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:05:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:05:57
Data point term sent to Coder	System	24 Aug 2020 19:04:38
Coding entries removed.	Heather Douds (b) (4) (b) (4)	24 Aug 2020 19:03:38
User entered 'Bumex' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	24 Aug 2020 19:03:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:33:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 12:33:32
Data point term sent to Coder	System	24 Aug 2020 12:33:02
User entered 'bumetanide'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'hypertension'	Stanley Doublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '1' reason for change: Data Entry Error	Heather Douds (b) (4)	24 Aug 2020 19:03:38
	(b) (4)	
User entered '2'	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Stanley Doublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'once daily (QD)'	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2012'	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:32:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	24 Aug 2020 12:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 12:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 12:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: PARASYMPATHOMIMETICS, PRODUCT: PILOCARPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:39:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:39:33
Data point term sent to Coder	System	24 Aug 2020 12:34:03
User entered 'pilocarpine'	Stanley Doublin (b) (4) (b) (4)	24 Aug 2020 12:33:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'sjogren's syndome'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:33:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '5'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'as needed (PRN)'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:33:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2004'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:33:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:33:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:33:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:33:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: MILNACIPRAN HYDROCHLORIDE, PRODUCTSYNONYM: SAVELLA - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Aug 2020 09:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Aug 2020 09:35:48
Data point term sent to Coder	System	24 Aug 2020 12:36:07
User entered 'savella'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'fibromyalgia'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '100'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'twice daily (BID)'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2008'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:35:35
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Aug 2020 12:35:35

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Aug 2020 12:35:35

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 12:35:35

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 12:38:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 12:38:41
Data point term sent to Coder	System	24 Aug 2020 12:37:08
User entered 'zolpidem'	Stanley Doublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'insomnia'	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '12.5' reason for change: Data Entry Error	Heather Douds (b) (4)	24 Aug 2020 19:48:05
User entered '72.5'	(b) (4)	
	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Stanley Doublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'as needed (PRN)'	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 15:50:13
	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2015'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:36:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:36:38
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:36:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:36:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:36:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Aug 2020 05:55:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Aug 2020 05:55:49
Data point term sent to Coder	System	24 Aug 2020 19:48:53
Coding entries removed.	Heather Douds (b) (4)	24 Aug 2020 19:48:28
	(b) (4)	
User entered 'CYCLOBENZAPRINE' reason for change: Data Entry Error	Heather Douds (b) (4)	24 Aug 2020 19:48:28
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 12:54:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 12:54:35
Data point term sent to Coder	System	24 Aug 2020 12:38:09
User entered 'cyclobenzaprine'	Stanley Doublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User closed query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN DUE TO FIBROMYALGIA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).		27 Oct 2020 05:32:53
Query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN DUE TO FIBROMYALGIA. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'related to fibromyalgia, accurate as entered' (Site from DM).	Heather Douds (b) (4)	23 Oct 2020 15:26:45
User opened query 'Per DM CLR: Please update the indication to specify the location of MUSCLE PAIN DUE TO FIBROMYALGIA. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:30:30
User entered 'muscle pain due to fibromyalgia'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '10'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'as needed (PRN)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2010'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:07
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:38:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:38:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:38:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 12:39:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 12:39:43
Data point term sent to Coder	System	24 Aug 2020 12:39:09
User entered 'benadryl'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'seasonal allergies'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '25'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'as needed (PRN)'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 15:50:13
	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2000'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:38:58

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:38:58
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	24 Aug 2020 12:38:58

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:38:58

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:38:58

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 12:38:58

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 12:40:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Aug 2020 12:40:35
Data point term sent to Coder	System	24 Aug 2020 12:40:10
User entered 'multivitamin'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 14:38:18
DataPoint Un-verified.	Stanley Dublin (b) (4)	11 Nov 2020 17:07:31
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	11 Nov 2020 17:07:31
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'health promotion'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'l'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'tablet (TABLET)'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'once daily (QD)'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2000'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Stanley Dublin (b) (4)	24 Aug 2020 12:39:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	24 Aug 2020 12:39:37

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Aug 2020 12:39:37

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 12:39:37

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NIFEDIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 18:26:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 18:26:39
Data point term sent to Coder User entered 'nifedipine ER'	System Joan Siegner (b) (4)	05 Sep 2020 18:25:52 05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'hypertension'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '60'	Joan Siegner (b) (4) [REDACTED]	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'once daily (QD)'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'un UNK 2013'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Joan Siegner (b) (4)	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 18:25:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 18:27:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 18:27:39
Data point term sent to Coder	System	05 Sep 2020 18:26:54
User entered 'Wellbutrin ER'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 05:45:37
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
Query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'No AE needed. Anxiety is ongoing since 2019, worsened by COVID. Has been on and off Wellbutrin since diagnosis ' (Site from DM).	Cassandra Zehenny (b) (4) (b) (4)	19 Oct 2020 18:35:36
User opened query 'Per CDM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 10:26:55
User entered 'anxiety'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '150'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'once daily (QD)'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '09 Sep 2020' reason for change: New Information	Heather Douds (b) (4)	10 Sep 2020 15:13:14
User entered '05 Sep 2020'	(b) (4)	
	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Sep 2020 18:26:00
	Joan Siegner (b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Joan Siegner (b) (4)	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 18:26:00

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: MOXIFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 05:51:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 05:51:51
Data point term sent to Coder	System	17 Sep 2020 20:51:19
User entered 'Moxifloxican'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	17 Sep 2020 20:50:19
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'retinal detachment'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'l'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'drop to L eye'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 15:34:38
User entered 'other (OTHER)'	Cassandra Zehenny (b) (4)	17 Sep 2020 20:50:19
	(b) (4)	
	Heather Douds (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per CDM: The Frequency is mentioned as "4X DAILY" Please clarify whether it mean four times daily. If yes, then update the frequency tab as it is one of the listed choices in frequency and other speify as blank.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:51:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
Query 'Per CDM: The Frequency is mentioned as "4X DAILY" Please clarify whether it mean four times daily. If yes, then update the frequency tab as it is one of the listed choices in frequency and other speify as blank.' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	28 Oct 2020 15:34:42
User entered empty; reason for change Per Query Resolution	Cassandra Zehenny (b) (4)	28 Oct 2020 15:34:38
User opened query 'Per CDM: The Frequency is mentioned as "4X DAILY" Please clarify whether it mean four times daily. If yes, then update the frequency tab as it is one of the listed choices in frequency and other speify as blank.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:57:50
User entered '4x daily'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 20:50:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 20:50:46
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Heather Douds (b) (4)	17 Sep 2020 20:50:46
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 20:50:19
User entered empty.	System	17 Sep 2020 20:50:19
	Heather Douds (b) (4)	17 Sep 2020 20:50:19
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '11 Sep 2020'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User closed query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:49:18
Query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Heather Douds (b) (4)	23 Oct 2020 15:27:56
User entered 'No (N)' reason for change: New Information	(b) (4)	23 Oct 2020 15:27:51
User opened query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:02:27
User entered 'Yes (Y)'	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '18 Sep 2020' reason for change: New Information	Heather Douds (b) (4)	23 Oct 2020 15:27:51
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	17 Sep 2020 20:50:19
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User entered '4'	System	28 Oct 2020 15:34:38
User entered empty.	System	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User entered 'l'	System	28 Oct 2020 15:34:38
User entered empty.	System	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:44
User entered '804 (804)'	System	28 Oct 2020 15:34:38
User entered empty.	System	17 Sep 2020 20:50:19

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE ACETATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 05:36:51
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 Sep 2020 05:36:51
Data point term sent to Coder	System	17 Sep 2020 20:52:20
User entered 'Prednisolone acetate'	Heather Douds (b) (4) (b) (4)	17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'retinal detachment'	Heather Douds (b) (4) (b) (4)	17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:17:48
User entered '1' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	05 Nov 2020 15:26:54
	(b) (4)	
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	05 Nov 2020 15:26:12
	(b) (4)	
User entered '2' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	05 Nov 2020 15:26:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '1'	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 17:17:58
User entered 'DROP' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	05 Nov 2020 15:26:54
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	05 Nov 2020 15:26:12
User entered 'DROPS' reason for change: Data Entry Error	(b) (4)	
	Cassandra Zehenny (b) (4)	05 Nov 2020 15:26:12
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'DROP TO L EYE 3X' reason for change: Data Entry Error	Heather Douds (b) (4)	23 Oct 2020 15:28:31
	(b) (4)	
User entered 'drop to L eye 4x'	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per DM CLR: It was noted in the response that it was "FOUR TIMES DAILY". However, the update is only three times daily. Note that "FOUR TIMES DAILY" is also available in the list of options for frequency. Please verify data and update as appropriate.' (Site from DM). Query 'Per DM CLR: It was noted in the response that it was "FOUR TIMES DAILY". However, the update is only three times daily. Note that "FOUR TIMES DAILY" is also available in the list of options for frequency. Please verify data and update as appropriate.' answered with 'Dosage has been decreased, data correct as entered' (Site from DM). User opened query 'Per DM CLR: It was noted in the response that it was "FOUR TIMES DAILY". However, the update is only three times daily. Note that "FOUR TIMES DAILY" is also available in the list of options for frequency. Please verify data and update as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Cassandra Zehenny (b) (4) (b) (4) (b) (4), (b) (6)	13 Nov 2020 08:11:38 11 Nov 2020 19:28:36 11 Nov 2020 15:26:01
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 17:17:44
User entered 'three times daily (TID)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4) Cassandra Zehenny (b) (4) (b) (4)	05 Nov 2020 15:26:54 05 Nov 2020 15:26:54
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'other (OTHER)'	Heather Douds (b) (4) (b) (4)	17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 06 Nov 2020 17:17:40
User closed query 'Per CDM: Thank you for the response. The "four times daily" is the one of the listed choices in the frequency. Kindly, update the data field and keep other specify blank. ' (Site from DM).		06 Nov 2020 02:06:58
Query 'Per CDM: Thank you for the response. The "four times daily" is the one of the listed choices in the frequency. Kindly, update the data field and keep other specify blank. ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	05 Nov 2020 15:27:01
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	05 Nov 2020 15:26:54
User entered empty; reason for change Data Entry Error	Cassandra Zehenny (b) (4)	05 Nov 2020 15:26:54
User opened query 'Per CDM: Thank you for the response. The "four times daily" is the one of the listed choices in the frequency. Kindly, update the data field and keep other specify blank. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:02:22
User closed query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once Daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:00:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
Query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once Daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'four times daily, not just daily' (Site from DM).	Heather Douds (b) (4)	23 Oct 2020 15:28:16

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "Once Daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM). User entered 'daily'	(b) (4), (b) (6) Heather Douds (b) (4) (b) (4)	23 Oct 2020 07:03:06 17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Intraocular (INTRAOCULAR)'	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '11 Sep 2020'	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User closed query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:49:38
Query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'still ongoing' (Site from DM).	Heather Douds (b) (4)	23 Oct 2020 15:32:51
User opened query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:03:16
User entered 'Yes (Y)'	Heather Douds (b) (4)	17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Heather Douds (b) (4) (b) (4)	17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Heather Douds (b) (4)	17 Sep 2020 20:51:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Nov 2020 15:26:54
User entered empty.	System	17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	05 Nov 2020 15:26:54
User entered empty.	System	17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 15:26:54
User entered empty.	System	17 Sep 2020 20:51:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Please add Restasis, Savella, Cozaar per PCP note on current meds (page 12 of PCP report). ' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 17:18:17
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
Query 'Please add Restasis, Savella, Cozaar per PCP note on current meds (page 12 of PCP report). ' answered with 'attempting to reach volunteer to confirm that these are actually current medications since they were not reported in visits 1 or 2. will update once we have more information. Thank you' (Site from CRA).	Cassandra Zehenny (b) (4)	01 Oct 2020 19:26:59
User opened query 'Please add Restasis, Savella, Cozaar per PCP note on current meds (page 12 of PCP report). ' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 15:29:51
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: MYDRIATICS AND CYCLOPLEGICS, ATC: ANTICHOLINERGICS, PRODUCT: CYCLOPENTOLATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Sep 2020 06:30:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Sep 2020 06:30:48
Data point term sent to Coder	System	17 Sep 2020 20:53:21
User entered 'Cyclopentolate 1%'	Heather Douds (b) (4)	17 Sep 2020 20:52:37

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'retinal detachment'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'l'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'drop to L eye'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'twice daily (BID)'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Intraocular (INTRAOCULAR)'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '12 Sep 2020'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User closed query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:49:56
Query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'still ongoing at this time per subject' (Site from DM).	Heather Douds (b) (4) (b) (4)	23 Oct 2020 15:34:19
User opened query 'Per DM CLR: The corresponding AE#2 has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:03:53
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	17 Sep 2020 20:52:37

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Heather Douds (b) (4)	17 Sep 2020 20:52:37
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 20:52:37

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 20:52:37

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 20:52:37

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:55:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 18:55:44
Data point term sent to Coder	System	02 Oct 2020 18:55:17
User entered 'Hydrochlorothiazide'	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 18:54:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Hypertension'	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '25'	Cassandra Zehenny (b) (4) (b) (4)	02 Oct 2020 18:54:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'once daily (QD)'	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	13 Nov 2020 14:50:35
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 14:46:05
DataPoint Verified.		28 Oct 2020 15:50:13
User entered 'l'	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Yes (Y)'	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	02 Oct 2020 18:54:54
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	02 Oct 2020 18:54:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 18:54:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 18:54:54

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 07:34:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 07:34:38
Data point term sent to Coder	System	02 Oct 2020 19:20:04
User entered 'Ibuprofen'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User closed query 'Please add meds administered during procedure on 06Oct' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 15:49:19
Query 'Please add meds administered during procedure on 06Oct' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	28 Oct 2020 15:34:53
User opened query 'Please add meds administered during procedure on 06Oct' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 15:22:06
User entered 'No (N)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Eye pain related to eye procedure'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '600'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'mg (mg)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Oral (ORAL)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:51:44
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:30
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:30
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '1 Oct 2020'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '0'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:51:46
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:30
User entered '02 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:30
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '2 Oct 2020'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User entered empty.	System	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User entered empty.	System	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:39
User entered empty.	System	02 Oct 2020 19:19:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: MYDRIATICS AND CYCLOPLEGICS, ATC: ANTICHOLINERGICS, PRODUCT: CYCLOPENTOLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:28:02
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 03:28:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
Data point term sent to Coder	System	28 Oct 2020 15:31:55
User entered 'Cyclopentolate 2%'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 15:50:13
	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Cryotherapy of right eye'	(b) (4), (b) (6)	28 Oct 2020 15:50:13
	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'l'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'drop in right eye'	(b) (4), (b) (6)	28 Oct 2020 15:31:31
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'as needed (PRN)'	(b) (4), (b) (6)	28 Oct 2020 15:31:31
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'ophthalmic solution'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	11 Nov 2020 14:51:56
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:42
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered '0'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 15:50:13
	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	11 Nov 2020 14:51:58
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:42
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 15:50:13
	Cassandra Zehenny (b) (4)	28 Oct 2020 15:31:31
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User entered empty.	System	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User entered empty.	System	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:53
User entered empty.	System	28 Oct 2020 15:31:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: MYDRIATICS AND CYCLOPLEGICS, ATC: SYMPATHOMIMETICS EXCL. ANTIGLAUCOMA PREPARATIONS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:08:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:08:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
Data point term sent to Coder	System	28 Oct 2020 15:32:56
User entered 'Phenylephrine 2.5%'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Cryotherapy of right eye'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'l'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'drop in right eye'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered empty.	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	(b) (4), (b) (6)	28 Oct 2020 15:32:38
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'ophthalmic solution'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	11 Nov 2020 14:52:05
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:52
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:52
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered '0'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	11 Nov 2020 14:52:07
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:52
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:35:52
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User entered empty.	System	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User entered empty.	System	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:56
User entered empty.	System	28 Oct 2020 15:32:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: MYDRIATICS AND CYCLOPLEGICS, ATC: ANTICHOLINERGICS, PRODUCT: TROPICAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:21:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:21:13
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
Data point term sent to Coder	System	28 Oct 2020 15:34:58
User entered 'tropicamide 1%'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Cryotherapy of right eye'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'l'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered 'drop in right eye'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'as needed (PRN)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:33:59
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'Other (OTHER)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'ophthalmic solution'	(b) (4), (b) (6)	28 Oct 2020 15:33:59
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	11 Nov 2020 14:52:15
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:36:02
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:36:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered '0'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 15:33:59
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	11 Nov 2020 14:52:17
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	09 Nov 2020 16:36:02
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	09 Nov 2020 16:36:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:50:13
User entered '6 Oct 2020'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:50:13
User entered 'No (N)'	Cassandra Zehenny (b) (4)	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User entered empty.	System	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User entered empty.	System	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:59
User entered empty.	System	28 Oct 2020 15:33:59

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	23 Nov 2020 16:24:21
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)	19 Nov 2020 13:12:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 13:12:57
Data point term sent to Coder	System	19 Nov 2020 13:12:05
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:35
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:37
User entered 'influenza prophylaxis'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:39
User entered 'l'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:40
User entered 'Other (OTHER)'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:42
User entered 'injection'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:43
User entered 'once (ONCE)'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:44
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:46
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:47
User entered empty.	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	23 Nov 2020 16:24:49
User entered '17 Nov 2020'	(b) (4), (b) (6)	
	Stanley Dublin (b) (4)	19 Nov 2020 13:11:55
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:51
User entered '0'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:53
User entered 'No (N)'	Stanley Doublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:54
User entered '17 Nov 2020'	Stanley Dublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:24:55
User entered 'No (N)'	Stanley Dublin (b) (4)	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User entered empty.	System	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User entered empty.	System	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:14:48
User entered empty.	System	19 Nov 2020 13:11:55

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:37
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RHEUMATOID ARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 06:52:45
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RHEUMATOID ARTHRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'medication change, not exacerbation' (Site from DM).	Heather Douds (b) (4) (b) (4)	25 Jan 2021 18:11:40
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening RHEUMATOID ARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:10:29
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: SELECTIVE IMMUNOSUPPRESSANTS, PRODUCT: LEFLUNOMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 22:39:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Dec 2020 22:39:41
Data point term sent to Coder	System	18 Dec 2020 18:26:57
User closed query 'For coding purposes, please verify the spelling of the medication LUFETIMIDE as it can not be referenced in the standard dictionary, and make your change to the reported term.' (Site from System).	System	18 Dec 2020 18:26:29

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'For coding purposes, please verify the spelling of the medication LUFETIMIDE as it can not be referenced in thje standar dictionary, and make your change to the reported term.' answered with 'updated' (Site from System).	Heather Douds (b) (4)	18 Dec 2020 18:26:29
User entered 'Leflunomide' reason for change: Data Entry Error	Heather Douds (b) (4)	18 Dec 2020 18:26:21
User opened query 'For coding purposes, please verify the spelling of the medication LUFETIMIDE as it can not be referenced in thje standar dictionary, and make your change to the reported term.' (Site from System).	Coder Import (b) (4)	18 Dec 2020 14:43:37
Data point term sent to Coder	System	04 Dec 2020 18:55:55
User entered 'lufetimide'	Stanley Doublin (b) (4)	04 Dec 2020 18:55:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered 'No (N)'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered 'rheumatoid arthritis'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered '10'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:37
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Dec 2020 18:55:51
	Stanley Dublin (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered empty.	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered 'once daily (QD)'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered empty.	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered empty.	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered '19 Nov 2020'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered '0'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered empty.	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 17:32:37
User entered 'No (N)'	Stanley Dublin (b) (4)	04 Dec 2020 18:55:51
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	04 Dec 2020 18:55:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Dec 2020 18:55:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 18:55:51

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:44
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)	11 Dec 2020 13:20:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 13:20:51
Data point term sent to Coder	System	04 Dec 2020 18:58:56
User entered 'prednisone'	Stanley Dublin (b) (4)	04 Dec 2020 18:58:40

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered 'fibromyalgia'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered '2.5'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered 'four times daily (QID)'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Dublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:44
User entered '26 Nov 2020'	Stanley Dublin (b) (4)	04 Dec 2020 18:58:40

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered '0'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Dublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:44
User entered '02 Dec 2020'	(b) (4), (b) (6)	02 Feb 2021 17:32:44
	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:44
User entered 'No (N)'	Stanley Doublin (b) (4)	04 Dec 2020 18:58:40

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User entered '4'	System	04 Dec 2020 18:58:40

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User entered '1'	System	04 Dec 2020 18:58:40

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:29
User entered '804 (804)'	System	04 Dec 2020 18:58:40

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:48
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)	11 Dec 2020 13:20:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 13:20:55
Data point term sent to Coder	System	04 Dec 2020 19:01:58
User entered 'prednisone'	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 17:32:48
	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered 'fibromyalgia'	(b) (4), (b) (6)	02 Feb 2021 17:32:48
	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered '7.5'	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered 'mg (mg)'	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:32:48
	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Feb 2021 17:32:48
	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:32:48
	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:32:48
	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered '04 Dec 2020'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered '0'	(b) (4), (b) (6)	02 Feb 2021 17:32:48
	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 16:32:06
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:48
User entered '09 Dec 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	17 Dec 2020 16:32:06
User entered empty.	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:48
User entered 'No (N)'	Stanley Doublin (b) (4)	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User entered 'I'	System	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User entered '1'	System	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:35
User entered '804 (804)'	System	04 Dec 2020 19:01:53

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
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)	17 Dec 2020 16:33:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 16:33:53
Data point term sent to Coder	System	17 Dec 2020 16:33:20
User entered 'prednisone'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered 'No (N)'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered 'fibromyalgia'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered '5'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered 'mg (mg)'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered empty.	Stanley Dublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered 'once daily (QD)'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered empty.	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered empty.	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered '10 Dec 2020'	Stanley Dublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered '0'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered 'No (N)'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered '16 Dec 2020'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:53
User entered 'No (N)'	Stanley Doublin (b) (4)	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User entered '1'	System	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User entered '1'	System	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:19
User entered '804 (804)'	System	17 Dec 2020 16:33:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:57
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)	17 Dec 2020 16:40:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Dec 2020 16:40:45
Data point term sent to Coder	System	17 Dec 2020 16:39:24
User entered 'prednisone'	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
User entered 'No (N)'	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
User entered 'fibromyalgia'	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
User entered '2.5'	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:57
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Feb 2021 17:32:57
	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
User entered empty.	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:57
User entered 'once daily (QD)'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:57
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:57
User entered empty.	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:57
User entered '17 Dec 2020'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:32:57
User entered '0'	(b) (4), (b) (6)	
	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	04 Jan 2021 15:06:50
User entered 'Yes (Y)'	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Jan 2021 15:06:50
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Jan 2021 15:06:36
User entered '23 Dec 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	04 Jan 2021 15:06:36
User entered empty.	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:57
User entered 'No (N)'	Stanley Doublin (b) (4)	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User entered '1'	System	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User entered '1'	System	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:24
User entered '804 (804)'	System	17 Dec 2020 16:39:22

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 18:53:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 18:53:21
Data point term sent to Coder	System	29 Dec 2020 17:47:33
User entered 'percocet [oxycodone / acetaminophen]'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered 'No (N)'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered 'lower back pain'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered '5/325'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered 'mg (mg)'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered 'as needed (PRN)'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered '24 Dec 2020'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered '0'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	04 Jan 2021 15:07:13
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered '27 Dec 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	04 Jan 2021 15:07:13
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:01
User entered 'No (N)'	Mikayla Frye (b) (4)	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User entered empty.	System	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User entered empty.	System	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:10
User entered empty.	System	29 Dec 2020 17:47:21

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 18:29:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 18:29:19
Data point term sent to Coder	System	29 Dec 2020 17:48:34
User entered 'diclofenac'	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:06
User entered 'No (N)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:06
User entered 'lower back pain'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:06
User entered '75'	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:06
User entered 'mg (mg)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:06
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:06
User entered 'twice daily (BID)'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:06
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:06
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:06
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:06
User entered '24 Dec 2020'	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:06
User entered '0'	(b) (4), (b) (6)	
	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Jan 2021 17:07:50
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	29 Dec 2020 17:48:10
	(b) (4)	
	Mikayla Frye (b) (4)	
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:06
User entered '12 Jan 2021' reason for change: Data Entry Error	Stanley Doublin (b) (4)	19 Jan 2021 17:07:50
User entered empty.	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:06
User entered 'No (N)'	Mikayla Frye (b) (4)	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User entered '2'	System	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User entered 'I'	System	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:13
User entered '804 (804)'	System	29 Dec 2020 17:48:10

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE NO. 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 12:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 12:51:44
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
Data point term sent to Coder	System	27 Jan 2021 14:59:42
User entered 'TYlenol #3 [acetaminophen/codeine]'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered 'No (N)'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered 'intraocular silicone implant removal - left eye'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered '300/30'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered 'mg (mg)'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered empty.	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:11
User entered 'as needed (PRN)'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	27 Jan 2021 14:59:31
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:11
User entered empty.	(b) (4), (b) (6)	
	Heather Douds (b) (4)	27 Jan 2021 14:59:31
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered 'Oral (ORAL)'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered empty.	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	02 Feb 2021 17:33:11
User entered '26 Jan 2021'	(b) (4), (b) (6)	
	Heather Douds (b) (4)	27 Jan 2021 14:59:31
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered '0'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered 'No (N)'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered '27 Jan 2021'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:33:11
User entered 'No (N)'	Heather Douds (b) (4)	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User entered empty.	System	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User entered empty.	System	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:15:39
User entered empty.	System	27 Jan 2021 14:59:31

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 13:42:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:42:32
Data point term sent to Coder	System	01 Apr 2021 15:18:49
User entered 'prednisone 2.5%'	Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'left eye cataract implant'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Other (OTHER)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'drop'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'four times daily (QID)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered '26 Mar 2021'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:06
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 15:18:28

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STERIODS, PRODUCT: NEPAFENAC, PRODUCTSYNONYM: NEVANAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 09:14:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 09:14:53
Data point term sent to Coder	System	01 Apr 2021 15:19:50
User entered 'nevanac 0.1%'	Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'left eye cataract implant'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Other (OTHER)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'drop'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'four times daily (QID)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered '26 Mar 2021'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:07
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 15:19:07

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 12:43:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:43:57
Data point term sent to Coder	System	01 Apr 2021 15:19:50
User entered 'meloxicam 0.5%'	Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'left eye cataract implant'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'l'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Other (OTHER)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'drop'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'four times daily (QID)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered '26 Mar 2021'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:58:09
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'No (N)'	(b) (4) Heather Douds (b) (4)	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 15:19:43

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC SODIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 10:06:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:06:44
Data point term sent to Coder	System	13 Apr 2021 14:29:48
User entered 'Diclofenac sodium'	Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Fall related pain'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '75'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'twice daily (BID)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '12 Apr 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Yes (Y)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 14:29:38

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 09:11:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:11:42
Data point term sent to Coder	System	13 Apr 2021 14:30:48
User entered 'cephalexin'	Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'abrasion to R brow bone'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '500'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'mg (mg)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'twice daily (BID)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'Oral (ORAL)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '12 Apr 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered '0'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:08
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	26 Apr 2021 14:17:01
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Heather Douds (b) (4)	26 Apr 2021 14:17:01
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
	(b) (4)	
User entered 'Yes (Y)'	Heather Douds (b) (4)	13 Apr 2021 14:30:17
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	26 Apr 2021 15:28:08
Signature has been broken.	(b) (4)	
	Heather Douds (b) (4)	26 Apr 2021 14:17:01
	(b) (4)	
User entered '17 Apr 2021' reason for change: New Information	Heather Douds (b) (4)	26 Apr 2021 14:17:01
	(b) (4)	
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
	(b) (4)	
User entered empty.	Heather Douds (b) (4)	13 Apr 2021 14:30:17
	(b) (4)	

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	16 Apr 2021 18:01:31
User entered 'No (N)'	(b) (4) Heather Douds (b) (4) (b) (4)	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 08:09:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 14:30:17

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:09:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:56:20
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:41:03
User entered 'Yes (Y)'	Heather Douds (b) (4) (b) (4)	12 Sep 2020 16:12:25

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:34:17
User entered '11 Sep 2020'	Heather Douds (b) (4)	12 Sep 2020 16:12:47
	(b) (4)	

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:34:19
User entered 'LEFT EYE Vitrectomy Membranectomy [retinal detachment repair]' reason for change: Data Entry Error	Heather Douds (b) (4)	17 Sep 2020 20:20:16
User entered 'Left eye retinal detachment repair'	(b) (4)	
	Heather Douds (b) (4)	12 Sep 2020 16:12:47
	(b) (4)	

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:34:20
User entered 'Adverse Event (AE)'	Heather Douds (b) (4) (b) (4)	12 Sep 2020 16:12:47

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:09:21

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:34:21
User entered empty.	Heather Douds (b) (4)	12 Sep 2020 16:12:47
	(b) (4)	

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:09:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:53:37
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:36:21
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4) (b) (4)	09 Nov 2020 16:36:21
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:26:20
Query 'Please verify the date. Should it be 06Oct, per PCP.' canceled (Site from CRA).		14 Oct 2020 20:42:20
User opened query 'Please verify the date. Should it be 06Oct, per PCP.' (Site from CRA).		14 Oct 2020 20:38:02
User entered '1 Oct 2020'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 20:43:56

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:09:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:26:20
User closed query 'Cryotherapy of right eye was done on 06Oct. Please add procedure to this eCRF. No source for Laser repair of right retial horseshoe tear done on 01Oct. Please provide to verify this procedure. ' (Site from CRA).		18 Oct 2020 02:17:19
Query 'Cryotherapy of right eye was done on 06Oct. Please add procedure to this eCRF. No source for Laser repair of right retial horseshoe tear done on 01Oct. Please provide to verify this procedure. ' answered with 'Sorry for the incorrect data entry. Updated. Thank you!' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	15 Oct 2020 15:24:16
User entered 'LASER photocoagulation REPAIR OF RIGHT RETINAL HORSESHOE TEAR' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	15 Oct 2020 15:24:00
User opened query 'Cryotherapy of right eye was done on 06Oct. Please add procedure to this eCRF. No source for Laser repair of right retial horseshoe tear done on 01Oct. Please provide to verify this procedure. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 20:58:08
User entered 'Laser REPAIR OF RIGHT RETINAL HORSESHOE TEAR' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Oct 2020 20:44:04
User entered 'Repair of right retinal horseshoe tear'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 20:43:56

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:49
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:26:20
User entered 'Adverse Event (AE)'	Heather Douds (b) (4) (b) (4)	02 Oct 2020 20:43:56

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:09:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:49
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:26:20
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:26:20
	Heather Douds (b) (4)	02 Oct 2020 20:43:56
	(b) (4)	

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:09:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:26:20
User entered '06 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	15 Oct 2020 15:25:48
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	15 Oct 2020 15:22:47
User entered '01 Oct 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	15 Oct 2020 15:22:47
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:47:35
User entered '9 Oct 2020'	Joan Siegner (b) (4)	12 Oct 2020 17:05:20

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:09:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	28 Oct 2020 15:26:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:26:20
	Cassandra Zehenny (b) (4)	15 Oct 2020 15:25:48
User entered 'Cryotherapy of right eye' reason for change: Data Entry Error	(b) (4)	15 Oct 2020 15:25:48
DataPoint Verified.	Cassandra Zehenny (b) (4)	15 Oct 2020 15:25:48
	(b) (4)	14 Oct 2020 20:47:36
User entered 'laser photocoagulation right eye'	(b) (4), (b) (6)	14 Oct 2020 20:47:36
	Joan Siegner (b) (4)	12 Oct 2020 17:05:20

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:47:38
User entered 'Adverse Event (AE)'	Joan Siegner (b) (4)	12 Oct 2020 17:05:20

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:09:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:54
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	14 Oct 2020 20:47:39
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 20:47:39
	Joan Siegner (b) (4)	12 Oct 2020 17:05:20

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:09:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:59
DataPoint Verified.		12 Apr 2021 20:45:43
User closed query 'Per DM CLR: Please review if this procedure was done for AE #2 RETINAL DETACHMENT OF LEFT EYE. If yes, please review the Date of this procedure, as it is out of the expected timeframe of AE #2 RETINAL DETACHMENT OF LEFT EYE (08 SEP 2020-12 SEP 2020). Please review and reconcile date of procedure, otherwise, there is no AE condition that matches this procedure. Review and update necessary ecfs as appropriate, or clarify as necessary. ' (Site from DM).		01 Mar 2021 07:37:19
Query 'Per DM CLR: Please review if this procedure was done for AE #2 RETINAL DETACHMENT OF LEFT EYE. If yes, please review the Date of this procedure, as it is out of the expected timeframe of AE #2 RETINAL DETACHMENT OF LEFT EYE (08 SEP 2020-12 SEP 2020). Please review and reconcile date of procedure, otherwise, there is no AE condition that matches this procedure. Review and update necessary ecfs as appropriate, or clarify as necessary. ' answered with 'Date is correct as entered. silicone implants are removed 4-6 months after placement' (Site from DM).	Cassandra Zehenny (b) (4)	25 Feb 2021 21:48:05
User opened query 'Per DM CLR: Please review if this procedure was done for AE #2 RETINAL DETACHMENT OF LEFT EYE. If yes, please review the Date of this procedure, as it is out of the expected timeframe of AE #2 RETINAL DETACHMENT OF LEFT EYE (08 SEP 2020-12 SEP 2020). Please review and reconcile date of procedure, otherwise, there is no AE condition that matches this procedure. Review and update necessary ecfs as appropriate, or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 09:57:27
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:09:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Jan 2021'	Heather Douds (b) (4) (b) (4)	27 Jan 2021 14:34:24

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:09:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:59
DataPoint Verified.		12 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Intraocular silicone implant removal - left eye'	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 14:34:24

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:59
DataPoint Verified.		12 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered 'Adverse Event (AE)'	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 14:34:24

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:09:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:01:59
DataPoint Verified.		12 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	27 Jan 2021 14:34:24

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:09:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:02:02
DataPoint Verified.		12 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered '26 Mar 2021'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:08:29

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:09:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:02:02
DataPoint Verified.		12 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'left eye cataract implant'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:08:29

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:09:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:02:02
DataPoint Verified.		12 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered 'Medical History (MH)'	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:08:29

US3552140

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:09:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:02:02
DataPoint Verified.		12 Apr 2021 20:45:43
User signature succeeded.	sharon frey (b) (4)	06 Apr 2021 15:11:41
User entered empty.	(b) (4) Heather Douds (b) (4) (b) (4)	01 Apr 2021 15:08:29

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:09:21

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:14
User signature succeeded.	sharon frey (b) (4) (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 15:40:45
User entered '21 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	21 Sep 2020 16:32:43

US3552140

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:09:21

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:32:14
DataPoint Verified.	(b) (4)	12 Apr 2021 17:04:25
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per CDM: Please confirm whether the primary reason for dosing discontinuation is AE(specify) or SAE(specify). As for AE #2 , Is this adverse event is serious = Yes. Review and update accordingly .' (Site from DM).	(b) (4)	
Query 'Per CDM: Please confirm whether the primary reason for dosing discontinuation is AE(specify) or SAE(specify). As for AE #2 , Is this adverse event is serious = Yes. Review and update accordingly .' answered with 'Done' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:00:11
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	30 Nov 2020 19:11:48
	(b) (4)	
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	30 Nov 2020 19:11:37
User opened query 'Per CDM: Please confirm whether the primary reason for dosing discontinuation is AE(specify) or SAE(specify). As for AE #2 , Is this adverse event is serious = Yes. Review and update accordingly .' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 12:08:03
	(b) (4), (b) (6)	09 Nov 2020 15:40:45
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Heather Douds (b) (4)	20 Oct 2020 14:18:20
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	(b) (4)	
	Stanley Doublin (b) (4)	21 Sep 2020 16:32:43
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:09:21

If reason is AE, SAE, 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 08:32:14
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:04:28
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User closed query 'Per CDM: For AE#2 - Is this adverse event is serious = Yes. Please review and update accordingly .' (Site from DM).	(b) (4)	(b) (4), (b) (6)
Query 'Per CDM: For AE#2 - Is this adverse event is serious = Yes. Please review and update accordingly .' answered with 'Done' (Site from DM).	Cassandra Zehenny (b) (4)	02 Dec 2020 09:01:03
DataPoint Un-verified.	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Nov 2020 19:11:52
	(b) (4)	
	Cassandra Zehenny (b) (4)	30 Nov 2020 19:11:37
	(b) (4)	
User entered 'SAE #2' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	30 Nov 2020 19:11:37
User opened query 'Per CDM: For AE#2 - Is this adverse event is serious = Yes. Please review and update accordingly .' (Site from DM).	(b) (4)	
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:21:34
DataPoint Verified.		
		22 Nov 2020 23:32:08
		19 Nov 2020 19:48:39
		19 Nov 2020 19:48:28
User closed query 'Please change to AE # 2 (actual line # for AE retinal detachment). ' (Site from CRA).		
Query 'Please change to AE # 2 (actual line # for AE retinal detachment). ' answered with 'updated' (Site from CRA).	Heather Douds (b) (4)	19 Nov 2020 19:11:43
DataPoint Un-verified.	(b) (4)	
	Heather Douds (b) (4)	19 Nov 2020 19:11:38
	(b) (4)	
User entered 'AE #2' reason for change: Per Query Resolution	Heather Douds (b) (4)	19 Nov 2020 19:11:38
	(b) (4)	
User opened query 'Please change to AE # 2 (actual line # for AE retinal detachment). ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:42:00
Query 'Please enter SAE #		
USA-US089-2020-MRNA-1273-P301000002'		19 Nov 2020 14:21:19
canceled (Site from CRA).		
User opened query 'Please enter SAE #		
USA-US089-2020-MRNA-1273-P301000002' (Site from CRA).		19 Nov 2020 01:51:20
DataPoint Verified.		18 Nov 2020 20:07:12

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:09:21

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Cassandra Zehenny (b) (4)	18 Nov 2020 17:34:53
DataPoint Un-verified.	Cassandra Zehenny (b) (4)	18 Nov 2020 17:34:48
User entered 'AE #1' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	18 Nov 2020 17:34:48
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:15:47
DataPoint Verified.		09 Nov 2020 15:40:45
User closed query 'Please remove "AE#1" to state only the AE term (RETINAL DETACHMENT SURGERY) ' (Site from CRA).		24 Oct 2020 23:22:16
Query 'Please remove "AE#1" to state only the AE term (RETINAL DETACHMENT SURGERY) ' answered with 'Updated per query request' (Site from CRA).	Cassandra Zehenny (b) (4)	20 Oct 2020 16:26:16
User entered 'RETINAL DETACHMENT SURGERY' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	20 Oct 2020 16:26:10
User opened query 'Please remove "AE#1" to state only the AE term (RETINAL DETACHMENT SURGERY) ' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 15:39:24
User entered 'AE #1 RETINAL DETACHMENT SURGERY' reason for change: Data Entry Error	Heather Douds (b) (4)	20 Oct 2020 14:18:20
User entered 'still recovering from recent retinal detachment surgery'	Stanley Dublin (b) (4)	21 Sep 2020 16:32:43

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'USA-US089-2020-MRNA-1273-P301000002'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:16
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:20
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:22
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:24
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:34
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 22:06:36

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:37
Reviewed for Safety.		18 Sep 2020 15:42:00
Amendment Manager: User entered 'frey'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:03
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:40
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:05
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:04
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:42
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:07
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'MO'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:06
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:43
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:08
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:14:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:20:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 11:26:06
User entered 'US' (non-conformant).	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '5'	(b) (4)	10 Nov 2020 14:54:18
User entered '4'	System	30 Oct 2020 12:16:06
User entered '3'	System	18 Sep 2020 15:42:15
User entered '2'	System	13 Sep 2020 11:26:18
User entered '1'	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'USA-US089-2020-MRNA-1273-P301000002'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:20
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:22
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:28
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:30
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:34
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:37
Reviewed for Safety.		18 Sep 2020 15:42:00
Amendment Manager: User entered 'frey'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:03
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:40
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:05
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:04
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:42
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:07
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'MO'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:06
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:43
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:08
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:14:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:20:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 11:26:06
User entered 'US' (non-conformant).	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '5'	(b) (4)	10 Nov 2020 14:54:18
User entered '4'	System	30 Oct 2020 12:16:06
User entered '3'	System	18 Sep 2020 15:42:15
User entered '2'	System	13 Sep 2020 11:26:18
User entered '1'	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:55:22
User entered '11/Sep/2020 09:55'	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	05 Nov 2020 20:55:24
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 11:26:06
User entered 'l'		11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'USA-US089-2020-MRNA-1273-P301000002'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:18
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:14:20
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:22
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:28
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:30
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:34
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'frey'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:03
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:40
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:05
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:04
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:42
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:07
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'MO'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:06
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:43
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:08
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:14:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:20:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 11:26:06
User entered 'US' (non-conformant).	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '5'	(b) (4)	10 Nov 2020 14:54:18
User entered '4'	System	30 Oct 2020 12:16:06
User entered '3'	System	18 Sep 2020 15:42:15
User entered '2'	System	13 Sep 2020 11:26:18
User entered '1'	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:55:27
User entered '13/Sep/2020 07:26'	System	13 Sep 2020 11:26:18

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	05 Nov 2020 20:55:29
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
User entered 'l'		13 Sep 2020 11:26:18

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'USA-US089-2020-MRNA-1273-P301000002'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:20
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:22
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:30
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:34
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'frey'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:03
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:40
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:05
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:04
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:42
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:07
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'MO'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:06
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:43
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:08
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:14:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:20:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 11:26:06
User entered 'US' (non-conformant).	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '5'	(b) (4)	10 Nov 2020 14:54:18
User entered '4'	System	30 Oct 2020 12:16:06
User entered '3'	System	18 Sep 2020 15:42:15
User entered '2'	System	13 Sep 2020 11:26:18
User entered '1'	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:55:35
User entered '18/Sep/2020 11:42'	System	18 Sep 2020 15:42:15

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	05 Nov 2020 20:55:37
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 12:15:58
User entered 'l'		18 Sep 2020 15:42:15

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'USA-US089-2020-MRNA-1273-P301000002'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:20
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:22
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:30
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:34
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'frey'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:03
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:40
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:05
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:04
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:42
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:07
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'MO'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:06
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:43
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:08
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:14:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:20:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 11:26:06
User entered 'US' (non-conformant).	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '5'	(b) (4)	10 Nov 2020 14:54:18
User entered '4'	System	30 Oct 2020 12:16:06
User entered '3'	System	18 Sep 2020 15:42:15
User entered '2'	System	13 Sep 2020 11:26:18
User entered '1'	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:55:41
User entered '30/Oct/2020 08:16'	System	30 Oct 2020 12:16:06

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.		05 Nov 2020 20:55:42
User entered 'l'		30 Oct 2020 12:16:06

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:14
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'USA-US089-2020-MRNA-1273-P301000002'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:16
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:18
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:20
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:22
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:28
Reviewed for Safety.	(b) (4), (b) (6)	11 Sep 2020 13:55:14
User entered 'No (N)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:30
Reviewed for Safety.		11 Sep 2020 13:55:14
User entered 'Yes (Y)'	System	11 Sep 2020 13:53:03

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 18:14:34
Reviewed for Safety.		18 Sep 2020 15:42:00
Amendment Manager: User entered 'sharon'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:37
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'frey'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:03
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:40
User entered '1100 S. Grand Blvd.' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:05
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:04
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:42
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:07
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	08 Oct 2020 18:14:39
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 15:42:00
Amendment Manager: User entered 'MO'	System	14 Sep 2020 22:06:36

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:33:06
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 14:29:43
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	11 Nov 2020 14:21:23
	(b) (4)	
Un-reviewed for Safety.	System	10 Nov 2020 14:54:18
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:53:59
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:30:08
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:33:55
	(b) (4)	

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Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:14:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:20:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Sep 2020 11:26:06
User entered 'US' (non-conformant).	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '5'	(b) (4)	10 Nov 2020 14:54:18
User entered '4'	System	30 Oct 2020 12:16:06
User entered '3'	System	18 Sep 2020 15:42:15
User entered '2'	System	13 Sep 2020 11:26:18
User entered '1'	System	11 Sep 2020 13:55:23

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:04:42
User entered '10/Nov/2020 09:54'	System	10 Nov 2020 14:54:18

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	11 Nov 2020 14:04:43
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 14:54:18

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'USA-US089-2020-MRNA-1273-P301000007'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:18
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'sharon'	System	05 Oct 2020 12:56:51

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Folder: SAE USA-US089-2020-MRNA-1273-P301000007

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:20
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'frey'	System	05 Oct 2020 12:56:51

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:38
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:58
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:21
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:39
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:59
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:23
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:22
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'MO'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

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Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:36
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:35:01
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered '63104' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:24
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15

US3552140

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:23
Reviewed for Safety.		13 Oct 2020 16:45:34
User entered 'US'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '6'	(b) (4)	19 Jan 2021 17:28:49
User entered '5'	System	24 Nov 2020 13:19:32
User entered '4'	System	10 Nov 2020 14:54:41
User entered '3'	System	29 Oct 2020 12:26:12
User entered '2'	System	13 Oct 2020 16:45:44
User entered '1'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:06
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered	System	05 Oct 2020 12:56:51
'USA-US089-2020-MRNA-1273-P301000007'		

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

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Form: Safety Report Form

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:09
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

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Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:11
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

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Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

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Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:15
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:18
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'sharon'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:20
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'frey'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:38
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:58
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:21
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:39
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:59
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:23
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:22
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'MO'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:36
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:35:01
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered '63104' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:24
User entered '63104'	(b) (4)	09 Nov 2020 16:34:15
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:23
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 16:45:34
User entered 'US'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '6'	(b) (4) System	19 Jan 2021 17:28:49
User entered '5'	System	24 Nov 2020 13:19:32
User entered '4'	System	10 Nov 2020 14:54:41
User entered '3'	System	29 Oct 2020 12:26:12
User entered '2'	System	13 Oct 2020 16:45:44
User entered '1'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:55:55
User entered '05/Oct/2020 13:26'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	05 Nov 2020 20:55:57
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 16:45:34
User entered 'l'		05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:06
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered	System	05 Oct 2020 12:56:51
'USA-US089-2020-MRNA-1273-P301000007'		

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:08
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:11
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:13
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:15
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:18
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'sharon'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'frey'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:38
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:58
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:21
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:39
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:59
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:23
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:22
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'MO'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:36
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:35:01
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:24
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:23
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 16:45:34
User entered 'US'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '6'	(b) (4) System	19 Jan 2021 17:28:49
User entered '5'	System	24 Nov 2020 13:19:32
User entered '4'	System	10 Nov 2020 14:54:41
User entered '3'	System	29 Oct 2020 12:26:12
User entered '2'	System	13 Oct 2020 16:45:44
User entered '1'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:56:00
User entered '13/Oct/2020 16:45'	System	13 Oct 2020 16:45:44

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	05 Nov 2020 20:56:02
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 12:26:03
User entered 'l'		13 Oct 2020 16:45:44

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'USA-US089-2020-MRNA-1273-P301000007'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:08
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:09
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:11
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:15
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:17
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:18
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'sharon'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:20
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'frey'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:38
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:34:58
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:21
User entered '1100 S. Grand Blvd'	(b) (4), (b) (6)	09 Nov 2020 16:34:15
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:39
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:34:59
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered 'Saint Louis' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:23
User entered 'St. Louis'	(b) (4)	09 Nov 2020 16:34:15
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:22
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'MO'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:36
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:35:01
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered '63104' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:24
User entered '63104'	(b) (4)	09 Nov 2020 16:34:15
	Cassandra Zehenny (b) (4)	
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:23
Reviewed for Safety.		13 Oct 2020 16:45:34
User entered 'US'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '6'	(b) (4) System	19 Jan 2021 17:28:49
User entered '5'	System	24 Nov 2020 13:19:32
User entered '4'	System	10 Nov 2020 14:54:41
User entered '3'	System	29 Oct 2020 12:26:12
User entered '2'	System	13 Oct 2020 16:45:44
User entered '1'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:56:07
User entered '29/Oct/2020 08:26'	System	29 Oct 2020 12:26:12

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Verified.		05 Nov 2020 20:56:10
User entered 'l'		29 Oct 2020 12:26:12

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:47:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'USA-US089-2020-MRNA-1273-P301000007'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:17
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:18
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'sharon'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:20
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'frey'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:38
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:58
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:21
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:39
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:59
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered 'Saint Louis' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:23
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:22
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'MO'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:36
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:35:01
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered '63104' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:24
User entered '63104'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:23
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 16:45:34
User entered 'US'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '6'	(b) (4) System	19 Jan 2021 17:28:49
User entered '5'	System	24 Nov 2020 13:19:32
User entered '4'	System	10 Nov 2020 14:54:41
User entered '3'	System	29 Oct 2020 12:26:12
User entered '2'	System	13 Oct 2020 16:45:44
User entered '1'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 01:59:00
User entered '10/Nov/2020 09:54'	System	10 Nov 2020 14:54:41

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 01:59:02
User entered 'l'		10 Nov 2020 14:54:41

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:06
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered	System	05 Oct 2020 12:56:51
'USA-US089-2020-MRNA-1273-P301000007'		

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:08
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:47:11
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:12
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:13
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:15
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:17
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 15:47:18
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'sharon'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:20
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'frey'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:38
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:58
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:21
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.		24 Nov 2020 18:33:39
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:59
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered 'Saint Louis' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:23
User entered 'St. Louis'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:22
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'MO'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:36
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:35:01
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered '63104' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:24
User entered '63104'	(b) (4)	09 Nov 2020 16:34:15
	Cassandra Zehenny (b) (4)	
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:23
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 16:45:34
User entered 'US'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '6'	(b) (4) System	19 Jan 2021 17:28:49
User entered '5'	System	24 Nov 2020 13:19:32
User entered '4'	System	10 Nov 2020 14:54:41
User entered '3'	System	29 Oct 2020 12:26:12
User entered '2'	System	13 Oct 2020 16:45:44
User entered '1'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:33:57
User entered '24/Nov/2020 13:19'	System	24 Nov 2020 13:19:32

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:59
User entered 'l'		24 Nov 2020 13:19:32

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'USA-US089-2020-MRNA-1273-P301000007'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:09
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:11
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:12
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:13
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:15
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'No (N)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:17
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'Yes (Y)'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:18
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'sharon'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 15:47:20
Reviewed for Safety.		05 Oct 2020 12:57:30
User entered 'frey'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:38
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.		12 Nov 2020 13:34:58
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	
User entered '1100 S. Grand Blvd' reason for change: Data Entry Error	Heather Douds (b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:54:26
DataPoint Un-verified.	System	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:21
User entered '1100 S. Grand Blvd'	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

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Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:39
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:34:59
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered 'Saint Louis' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:23
User entered 'St. Louis'	(b) (4)	09 Nov 2020 16:34:15
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:22
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:57:30
User entered 'MO'	System	05 Oct 2020 12:56:51

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
Reviewed for Safety.	(b) (4)	19 Jan 2021 17:28:37
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:33:36
Un-reviewed for Safety.	System	24 Nov 2020 13:19:32
DataPoint Un-verified.	System	24 Nov 2020 13:19:32
User entered empty.	System	24 Nov 2020 13:19:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:19:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 13:35:01
Un-reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
User entered '63104' reason for change: Data Entry Error	(b) (4)	12 Nov 2020 13:02:57
Reviewed for Safety.	Heather Douds (b) (4)	12 Nov 2020 13:02:57
	(b) (4)	10 Nov 2020 14:54:26
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 14:54:18
User entered empty.	System	10 Nov 2020 14:54:18
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:32:24
User entered '63104'	(b) (4)	09 Nov 2020 16:34:15
	Cassandra Zehenny (b) (4)	09 Nov 2020 16:34:15
	(b) (4)	

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4)	30 Oct 2020 15:47:23
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 16:45:34
User entered 'US'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:09:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
User entered '6'	(b) (4) System	19 Jan 2021 17:28:49
User entered '5'	System	24 Nov 2020 13:19:32
User entered '4'	System	10 Nov 2020 14:54:41
User entered '3'	System	29 Oct 2020 12:26:12
User entered '2'	System	13 Oct 2020 16:45:44
User entered '1'	System	05 Oct 2020 13:26:35

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:09:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:14
User entered '19/Jan/2021 17:28'	System	19 Jan 2021 17:28:49

US3552140

Folder: SAE USA-US089-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:09:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	sharon frey (b) (4)	21 Feb 2021 17:56:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:16
User entered 'I'		19 Jan 2021 17:28:49