

US3592196 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:57:06

All time stamps listed in this document are displayed in GMT

US3592196

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 08:32:57

Generated On: 11 Aug 2021 22:57:06

[Participant ID](#)

US3592196

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

US3592196

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:42:16

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Date of Informed Consent (<i>dd MMM yyyy</i>)	16 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) 19 Feb 2021 16:42:16

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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) 19 Feb 2021 16:42:16

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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) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Condition	HYPOKALEMIA
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 (8)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Condition	NAUSEA
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Start Year (derived)	1991
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Condition	POSTMENOPAUSAL
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 (11)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Condition	HEADACHES OCCASIONALLY
Start date (dd MMM yyyy)	UN UNK 1957
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 1957
Start Year (derived)	1957
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Condition	CONSTIPATION
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: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 AUG 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 10:20
Height (xxx.x)	155.0 cm
Weight (xxx.x)	67.3 kg
BMI (xxx.x)	28.01249 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) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 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) 19 Feb 2021 16:42:16

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Date of assessment (dd MMM yyyy) 16 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 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

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

GOES OUT IN PUBLIC TO
GROCERY STORE, DR OFFICE ,
ECT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:42:16

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

What was the date of randomization? (dd MMM yyyy) 16 AUG 2020

What was the participant's randomization number? 186506

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) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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)	16 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 10:32
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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)	16 AUG 2020
Time of assessment (00:00-23:59)	12:07 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:07
Temperature (xxx.x)	95.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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) 16 AUG 2020

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 16 AUG 2020 11:35

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) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 AUG 2020

Collection time (00:00-23:59)

10:57 (24 HR)

Collection date and time (derived)

16 AUG 2020 10:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)			16 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:35	16 AUG 2020 10:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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

95.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:16

PC Open Date & Time

16 AUG 2020 11:55

PC Close Date & Time

16 AUG 2020 14:25

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 17 AUG 2020 08:26

PC Open Date & Time 16 AUG 2020 15:20

PC Close Date & Time 17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

17 AUG 2020 18:30

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

18 AUG 2020 18:35

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

19 AUG 2020 20:05

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	20 AUG 2020 17:29
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 18:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

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

97.9 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 AUG 2020 20:57

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

23 AUG 2020 18:08

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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

16 AUG 2020 12:17

PC Open Date & Time

16 AUG 2020 11:55

PC Close Date & Time

16 AUG 2020 14:25

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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

17 AUG 2020 08:25

PC Open Date & Time

16 AUG 2020 15:20

PC Close Date & Time

17 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

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

17 AUG 2020 18:17

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

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

18 AUG 2020 18:30

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

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

19 AUG 2020 20:02

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

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

20 AUG 2020 17:07

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

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

21 AUG 2020 18:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

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

22 AUG 2020 20:56

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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

No ☒

Yes ☐

PC Time stamp	16 AUG 2020 12:18
PC Open Date & Time	16 AUG 2020 11:55
PC Close Date & Time	16 AUG 2020 14:25

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 08:26
PC Open Date & Time	16 AUG 2020 15:20
PC Close Date & Time	17 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

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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Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 18:31
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:01
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 17:06
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 18:05
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

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)

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 20:58
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 23 AUG 2020 18:06

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3592196

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 AUG 2020 18:05
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3592196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:27:52

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:27:52

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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)	13 SEP 2020
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	13 SEP 2020 09:50
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)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 SEP 2020

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

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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?

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?

US3592196

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 SEP 2020

Collection time (00:00-23:59)

10:17 (24 HR)

Collection date and time (derived)

13 SEP 2020 10:17

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)			13 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:19	13 SEP 2020 10:19
Nasopharyngeal Swab 2	No		

US3592196

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:27:52

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:27:52

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:56:37

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:56:37

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:42:16

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	11:37 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:37
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592196

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

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.

US3592196

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

11:53 (24 HR)

Collection date and time (derived)

13 OCT 2020 11:53

US3592196

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:42:17

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 OCT 2020 17:31:57
Patient Cloud Open Date & Time	16 OCT 2020 00:01
Patient Cloud Close Date & Time	20 OCT 2020 23:59

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

24 OCT 2020 14:23:15

Patient Cloud Open Date & Time

23 OCT 2020 00:01

Patient Cloud Close Date & Time

27 OCT 2020 23:59

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 04:47:33
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 NOV 2020 09:05:00
Patient Cloud Open Date & Time	13 NOV 2020 00:01
Patient Cloud Close Date & Time	17 NOV 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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	19 NOV 2020 09:31:58
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 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	25 NOV 2020 08:18:54
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 16:37:26
Patient Cloud Open Date & Time	01 DEC 2020 00:01
Patient Cloud Close Date & Time	05 DEC 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 DEC 2020 18:49:41
Patient Cloud Open Date & Time	08 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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	15 DEC 2020 11:29:04
Patient Cloud Open Date & Time	15 DEC 2020 00:01
Patient Cloud Close Date & Time	19 DEC 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 07:40:02

Patient Cloud Open Date & Time

22 DEC 2020 00:01

Patient Cloud Close Date & Time

26 DEC 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 DEC 2020 07:11:52
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

05 JAN 2021 08:26:18

Patient Cloud Open Date & Time

05 JAN 2021 00:01

Patient Cloud Close Date & Time

09 JAN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

12 JAN 2021 08:32:45

Patient Cloud Open Date & Time

12 JAN 2021 00:01

Patient Cloud Close Date & Time

16 JAN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 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	19 JAN 2021 23:01:30
Patient Cloud Open Date & Time	19 JAN 2021 00:01
Patient Cloud Close Date & Time	23 JAN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 JAN 2021 01:20:27
Patient Cloud Open Date & Time	26 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

02 FEB 2021 09:12:03

Patient Cloud Open Date & Time

02 FEB 2021 00:01

Patient Cloud Close Date & Time

06 FEB 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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	09 FEB 2021 18:47:45
Patient Cloud Open Date & Time	09 FEB 2021 00:01
Patient Cloud Close Date & Time	13 FEB 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

16 FEB 2021 10:23:07

Patient Cloud Open Date & Time

16 FEB 2021 00:01

Patient Cloud Close Date & Time

20 FEB 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 FEB 2021 15:58:50

Patient Cloud Open Date & Time

23 FEB 2021 00:01

Patient Cloud Close Date & Time

27 FEB 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

02 MAR 2021 10:57:20

Patient Cloud Open Date & Time

02 MAR 2021 00:01

Patient Cloud Close Date & Time

06 MAR 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

09 MAR 2021 10:57:54

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

16 MAR 2021 08:07:44

Patient Cloud Open Date & Time

16 MAR 2021 00:01

Patient Cloud Close Date & Time

20 MAR 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 23:51:37

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

30 MAR 2021 08:03:04

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 APR 2021 10:50:31
Patient Cloud Open Date & Time	06 APR 2021 00:01
Patient Cloud Close Date & Time	10 APR 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

13 APR 2021 09:37:49

Patient Cloud Open Date & Time

13 APR 2021 00:01

Patient Cloud Close Date & Time

17 APR 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 19:45:27

Patient Cloud Open Date & Time

20 APR 2021 00:01

Patient Cloud Close Date & Time

24 APR 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

27 APR 2021 09:13:41

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 <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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

10 JUL 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 <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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

14 AUG 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

09 OCT 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

30 OCT 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

18 DEC 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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12 FEB 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 <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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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26 FEB 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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="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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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05 MAR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 MAR 2022 00:01

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12 MAR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 MAR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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02 APR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐
Yes ☐

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 APR 2022 00:01

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09 APR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

30 APR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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07 MAY 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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25 JUN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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02 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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09 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

30 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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20 AUG 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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27 AUG 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2022 00:01

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03 SEP 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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10 SEP 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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17 SEP 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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 ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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11 OCT 2022 00:01

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15 OCT 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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"/>

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2022 23:59

US3592196

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:57:06

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 21:34:38

US3592196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:53:31

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:53:31

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

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

Visit date (dd MMM yyyy)	2 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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US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 MAR 2021
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	02 MAR 2021 15:15
Temperature (xxx.x)	36.7 C
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)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592196

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

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.

US3592196

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

15:31 (24 HR)

Collection date and time (derived)

2 MAR 2021 15:31

US3592196

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:54:32

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:54:32

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 08:32:57

Generated On: 11 Aug 2021 22:57:06

Date of Contact									
Time of Contact									
Date and Time of Contact (derived)									
Type of Contact	<table><tr><td>Clinic Visit - Scheduled</td><td><input type="checkbox"/></td></tr><tr><td>Clinical Visit - Unscheduled</td><td><input type="checkbox"/></td></tr><tr><td>Safety Call</td><td><input type="checkbox"/></td></tr><tr><td>Convalescent Tele-visit</td><td><input type="checkbox"/></td></tr></table>	Clinic Visit - Scheduled	<input type="checkbox"/>	Clinical Visit - Unscheduled	<input type="checkbox"/>	Safety Call	<input type="checkbox"/>	Convalescent Tele-visit	<input type="checkbox"/>
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?	<table><tr><td>Yes</td><td><input type="checkbox"/></td></tr><tr><td>No</td><td><input type="checkbox"/></td></tr></table>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>				
Yes	<input type="checkbox"/>								
No	<input type="checkbox"/>								

US3592196

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

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

US3592196

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Date of updated informed consent (<i>dd MMM yyyy</i>)	4 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>)	4 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 checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3592196

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Height	ND - Not Done
Weight	68.1 kg
BMI (xxx.x)	

US3592196

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Height	ND - Not Done
Weight	68.1 kg
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)	4 FEB 2021
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 09:30
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3592196

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Height	ND - Not Done
Weight	68.1 kg
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)	4 FEB 2021
Time of assessment (00:00-23:59)	10:33 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 10:33
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3592196

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 FEB 2021

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

US3592196

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

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) 4 FEB 2021

What was the treatment time? (00:00-23:59) 10:01 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 10:01

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

US3592196

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 FEB 2021
Collection time (00:00-23:59)	09:45 (24 HR)
Collection date and time (derived)	4 FEB 2021 09:45

US3592196

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 FEB 2021
Collection time (00:00 - 23:59)	09:47
Collection Date and Time (derived)	4 FEB 2021 09:47

US3592196

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag 1

OLD29 Placebo Flag 1

US3592196

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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	OLD29

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

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)	2 MAR 2021
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 15:15
Temperature (xxx.x)	36.7 C
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)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

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)	2 MAR 2021
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	2 MAR 2021 16:30
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3592196

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 MAR 2021

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

US3592196

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

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) 2 MAR 2021

What was the treatment time? (00:00-23:59) 15:58 (24 HR)

Treatment Date and Time (derived) 2 MAR 2021 15:58

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

US3592196

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592196

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 08:33:38

Generated On: 11 Aug 2021 22:57:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

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

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 MAR 2021
Time of assessment (00:00-23:59)	13:14 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 13:14
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592196

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

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.

US3592196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

13:20 (24 HR)

Collection date and time (derived)

29 MAR 2021 13:20

US3592196

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 15:53:56

Generated On: 11 Aug 2021 22:57:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:53:56

Generated On: 11 Aug 2021 22:57:06

AEID	
Adverse event	ASYMPTOMATIC COVID-19 POSITIVE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 AUG 2020
Start time (00:00-23:59)	10:35 (24 HR)
AE start date and time (derived)	16 AUG 2020 10:35
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 AUG 2020
End time (00:00-23:59)	23:59 (24 HR)
AE End Date and Time (derived)	28 AUG 2020 23:59
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:53:56

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 15:53:56

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AEID

Adverse event

ACID REFLUX

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

8 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

3 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 15:53:56

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	_____

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 15:53:58

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:53:57

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Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 15:53:57

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1970
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) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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 1993
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 (10)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSAL

Dose per administration 0.5

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
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) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication MEDROXYPROGESTERONE

Prophylaxis Yes ☐
No ☒

Indication POST MENOPAUSAL

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 (11)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:53:57

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Name of Medication SOLIFENACIN

Prophylaxis Yes ☐
No ☒

Indication NOCTURIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication POTASSIUM CHLORIDE ER

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 10

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

If dose unit is Other, specify MEQ

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) 16 Apr 2021 15:53:57

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 (14)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication GLUCOSAMINE CHONDROITIN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

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 (14)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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)	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 (15)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication CALCIUM WITH VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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 (18)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

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 (18)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

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 (19)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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)	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 (20)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPLEMENT

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) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication FIBROMYALGIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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 JAN 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 (22)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication NAPROXEN SODIUM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 440

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) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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 1990	
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 (23)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication SIMETHICONE

Prophylaxis Yes ☐
No ☒

Indication EXCESS STOMACH GAS

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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 (24)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication DIPHENHYDRAMINE

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 (24)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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	1990
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 (25)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication PSEUDOEPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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	1990
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 (26)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 440

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 (26)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 AUG 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

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 (28)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 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 (29)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication RESTASIS

Prophylaxis Yes ☐
No ☒

Indication DRY EYE

Dose per administration 1

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

If dose unit is Other, specify GTT

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 (29)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 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)	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 (30)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication L-LYSINE

Prophylaxis Yes ☒
No ☐

Indication COLD SORES PROPHYLAXIS

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 (30)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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)	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 (31)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

Name of Medication CORTISONE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

3 MONTHS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:57:06

	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		INTRA-ARTICULAR INJECTION
Start date (dd MMM yyyy)	28 JAN 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)		
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 15:53:58

Generated On: 11 Aug 2021 22:57:06

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 28 Apr 2021 08:32:57

Generated On: 11 Aug 2021 22:57:06

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input checked="" type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	True
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	True
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	False
Dosing Discontinuation	False

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 28 Apr 2021 08:32:57

Generated On: 11 Aug 2021 22:57:06

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	13 SEP 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	True
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3592196

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Apr 2021 08:32:58

Generated On: 11 Aug 2021 22:57:06

Date of dosing discontinuation (dd MMM yyyy) 16 AUG 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input 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 checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:57:06

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 ☐

Audit

US3592196 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

US3592196

Form: Participant Creation

Generated On: 11 Aug 2021 22:57:06

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 16:56:35
User entered 'US3592196'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 14:59:10

US3592196

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:40:07

US3592196

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:13
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 14:59:11

US3592196

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Aug 2020 16:40:07

US3592196

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'SCRN'	System	16 Aug 2020 16:40:07

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 14:59:12

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered '69'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'YEARS'	System	16 Aug 2020 16:40:19

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '69'	System	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered 'Female (F)'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered 'l'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:19

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:57:06

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:32
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:40
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Aug 2020'	System	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '2020'	System	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:40
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:40
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:40
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:40
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 14:59:11

US3592196

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:57:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'l'	System	16 Aug 2020 16:40:36

US3592196

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:40:36

US3592196

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:57:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:57:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:39:36

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:41:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:41:29
Data point term sent to Coder	System	19 Aug 2020 14:40:41
User entered 'penicillin allergy'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 1969'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 1969'	System	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '1969'	System	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:41:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:41:28
Data point term sent to Coder	System	19 Aug 2020 14:40:44
User entered 'bilateral hearing loss'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 2010'	System	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '2010'	System	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User closed query 'Please specify which eye or both eyes.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 16:58:34
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eye - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 21:09:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 21:09:04
Query 'Please specify which eye or both eyes.' answered with 'done' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 21:08:06
Data point term sent to Coder	System	08 Jan 2021 21:08:04
Coding entries removed.	(b) (4), (b) (6)	08 Jan 2021 21:08:02
User entered 'DRY EYE, bilateral' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:08:02
User opened query 'Please specify which eye or both eyes.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 22:19:21
Query 'Per DM CLR: Please specify the laterality of DRY EYE (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.	(b) (4), (b) (6)	06 Nov 2020 15:30:43
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please specify the laterality of DRY EYE (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.	(b) (4), (b) (6)	28 Sep 2020 05:05:48
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eye - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:41:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:41:30
Data point term sent to Coder	System	19 Aug 2020 14:40:44
User entered 'dry eye'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 2010'	System	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '2010'	System	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:42:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:42:20
Data point term sent to Coder	System	19 Aug 2020 14:41:45
User entered 'seasonal allergies'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 1990'	System	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '1990'	System	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:46:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:46:25
Data point term sent to Coder	System	19 Aug 2020 14:44:56
User entered 'hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 14:45:03
User entered 'Un UNK 1969' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 14:45:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 14:44:54
User entered 'uu UNK 1969' (non-conformant).	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 1969'	System	19 Aug 2020 14:45:03
User entered empty.	System	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '1969'	System	19 Aug 2020 14:45:03
User entered empty.	System	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:46:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:46:26
Data point term sent to Coder	System	19 Aug 2020 14:45:57
User entered 'hypokalemia'	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 14:48:45
User entered 'UN UNK 2015' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 14:48:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 14:45:18
User entered 'un UNK 215' (non-conformant).	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 2015'	System	19 Aug 2020 14:48:45
User entered empty.	System	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '2015'	System	19 Aug 2020 14:48:45
User entered empty.	System	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:11:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:11:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:46:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:46:26
Data point term sent to Coder	System	19 Aug 2020 14:45:57
User entered 'nausea'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 1991'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 1991'	System	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '1991'	System	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Flatulence, bloating and distension, PT: Flatulence, LLT: Gas in stomach - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 16:59:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 16:59:56
Data point term sent to Coder	System	08 Jan 2021 21:18:09
Coding entries removed.	(b) (4), (b) (6)	08 Jan 2021 21:17:25
User entered 'OCCASIONAL EXCESS STOMACH GAS' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:17:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Flatulence, bloating and distension, PT: Flatulence, LLT: Gas - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:35:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:35:08
Data point term sent to Coder	System	19 Aug 2020 14:45:57
User entered 'occasional excess gas'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 2010'	System	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '2010'	System	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:48:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:48:21
Data point term sent to Coder	System	19 Aug 2020 14:46:58
User entered 'postmenopausal'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 2000'	System	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '2000'	System	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Nocturia, LLT: Nocturia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:48:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:48:21
Data point term sent to Coder	System	19 Aug 2020 14:46:58
User entered 'nocturia'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 2000'	System	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '2000'	System	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:48:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:48:21
Data point term sent to Coder	System	19 Aug 2020 14:46:59
User entered 'osteoarthritis general'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'UN UNK 1990' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:15:17
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 1990'	System	08 Jan 2021 21:15:17
User entered 'Jan 2005'	System	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '1990'	System	08 Jan 2021 21:15:17
User entered '2005'	System	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
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)	19 Aug 2020 14:48:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:48:21
Data point term sent to Coder	System	19 Aug 2020 14:46:59
User entered 'fibromyalgia'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 1993'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 1993'	System	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '1993'	System	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:50:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:50:23
Data point term sent to Coder	System	19 Aug 2020 14:46:59
User entered 'headaches occasionally'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 1957'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

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Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 1957'	System	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '1957'	System	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:06:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 20:06:29
Data point term sent to Coder	System	06 Oct 2020 20:04:55
User entered 'constipation'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'un UNK 2000'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:02:32
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'Jan 2000'	System	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '2000'	System	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered empty.	System	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered '10:20'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered '16 Aug 2020 10:20'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered '155.0' cm	(b) (4), (b) (6)	19 Aug 2020 14:48:33
DataPoint set to visible.	System	16 Aug 2020 16:40:36

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered '67.3' kg	(b) (4), (b) (6)	19 Aug 2020 14:48:33
DataPoint set to visible.	System	16 Aug 2020 16:40:36

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
Amendment Manager: User entered '28.01249'	System	16 Sep 2020 23:59:07
User entered '28.0'	System	19 Aug 2020 14:48:33
DataPoint set to visible.	System	16 Aug 2020 16:40:36

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'kg/m2'	System	19 Aug 2020 14:48:33
DataPoint set to visible.	System	16 Aug 2020 16:40:36

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 11:14:05
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'data corrected' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 19:01:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:05
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 06:40:42
User entered '97.4' F	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:05
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:05
User entered '78'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'bpm'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:05
User entered '12'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'breaths/min'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:05
User entered '119'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'mmHg'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:05
User entered '61'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User entered 'mmHg'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24

US3592196

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 22:15:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:49:17

US3592196

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:50
User entered '16 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 22:15:37
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:49:17

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:55
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:06

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:55
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:06

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:55
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:06

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:55
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:55
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:06

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:55
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:55
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:57:06

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:03:55
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 14:50:49
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User closed query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System).	System	19 Aug 2020 14:50:49
User opened query 'Other specified is provided for Occupational Risk , but OTHER is not selected for Occupational Risks. Please reconcile.' (Site from System).	System	19 Aug 2020 14:50:38
User entered 'goes out in public to grocery store, dr office , ect'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:57:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:48:24
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:09
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:51:10

US3592196

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:14
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:51:10

US3592196

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:14
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 14:51:10

US3592196

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'VISIT1'	System	19 Aug 2020 14:51:10

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:09:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:54:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:54:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Aug 2020 16:09:14
User entered '186506' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:09:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	16 Aug 2020 16:09:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:57:06

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:04:23
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 20:13:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:33:20

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	26 Aug 2020 22:05:38
change Data Entry Error		
User entered '155.0' cm	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 22:05:38
User entered '67.3' kg	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 22:05:38
User entered '155.0' cm	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 22:05:38
User entered '67.3' kg	(b) (4), (b) (6)	19 Aug 2020 14:57:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '10:32'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered '16 Aug 2020 10:32'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '97.4' F	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '78'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'bpm'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '12'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'breaths/min'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '119'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'mmHg'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '61'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'mmHg'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	26 Aug 2020 22:05:38
change Data Entry Error		
User entered '155.0' cm	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	26 Aug 2020 22:05:38
User entered '67.3' kg	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:53:59
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 mins post dose ' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 14:57:49
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	19 Aug 2020 14:57:01
User entered '12:07'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered '16 Aug 2020 12:07'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User closed query 'Per CDM: Temperature is out of range. kindly specify CS or NCS. If CS, consider adding an AE.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:04:53
Query 'Per CDM: Temperature is out of range. kindly specify CS or NCS. If CS, consider adding an AE.' answered with 'not clinically significant ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:13:39
User opened query 'Per CDM: Temperature is out of range. kindly specify CS or NCS. If CS, consider adding an AE.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 06:52:07
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 06:51:04
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Confirm correct as entered' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 19:51:25
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:59:07
User entered '95.0' F	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '87'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'bpm'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '16'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'breaths/min'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '135'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'mmHg'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:15
User entered '65'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'mmHg'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 22:15:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:54:38

US3592196

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 22:15:50
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:54:38

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:38
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:38
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'MRNA-1273 OR PLACEBO'	System	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:38
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:38
User entered '11:35'	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered '16 Aug 2020 11:35'	System	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:38
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 17:06:38
User entered 'ONCE'	System	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'INTRAMUSCULAR'	System	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:54:57

US3592196

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:42
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:54:57

US3592196

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:42
User entered '10:57'	(b) (4), (b) (6)	19 Aug 2020 14:54:57

US3592196

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered '16 Aug 2020 10:57'	System	19 Aug 2020 14:54:57

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:46
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 14:55:18
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	19 Aug 2020 14:55:18
User entered '16 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 14:55:18
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 14:55:07
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:46
User entered '10:35'	(b) (4), (b) (6)	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered '16 Aug 2020 10:35'	System	19 Aug 2020 14:55:18
User entered empty.	System	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:46
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:46
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered empty.	System	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:06:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:55:22

US3592196

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'I'	System	19 Aug 2020 14:55:22

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:16:11', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '6815b7ed-3ba2-4331-ac75-e8b8e82283bb' User entered 'Yes (Y)'	System	16 Aug 2020 17:16:47
	System	16 Aug 2020 17:16:47

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:16:29', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '6815b7ed-3ba2-4331-ac75-e8b8e82283bb' User entered '95.0'	System	16 Aug 2020 17:16:47
	System	16 Aug 2020 17:16:47

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:16:35', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '6815b7ed-3ba2-4331-ac75-e8b8e82283bb' User entered 'No (N)'	System	16 Aug 2020 17:16:47
	System	16 Aug 2020 17:16:47

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:16:44', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '6815b7ed-3ba2-4331-ae75-e8b8e82283bb' User entered '16 Aug 2020 12:16'	System	16 Aug 2020 17:16:47
	System	16 Aug 2020 17:16:47

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 11:55'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 14:25'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:37', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '6239bcf5-450d-4faf-9d76-44807a4b9c90' User entered 'No (N)'	System	17 Aug 2020 13:26:48
	System	17 Aug 2020 13:26:48

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:41', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '6239bcf5-450d-4faf-9d76-44807a4b9c90'	System	17 Aug 2020 13:26:48
User entered 'No (N)'	System	17 Aug 2020 13:26:48

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:45', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '6239bcf5-450d-4faf-9d76-44807a4b9c90'	System	17 Aug 2020 13:26:48
User entered '17 Aug 2020 08:26'	System	17 Aug 2020 13:26:48

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 15:20'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 2'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:30:20', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '3b4b4d34-612d-4b31-896a-44bce05f25ff' User entered 'Yes (Y)'	System	17 Aug 2020 23:30:45
	System	17 Aug 2020 23:30:45

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:30:31', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '3b4b4d34-612d-4b31-896a-44bce05f25ff' User entered '98.9'	System	17 Aug 2020 23:30:45
	System	17 Aug 2020 23:30:45

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:30:35', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '3b4b4d34-612d-4b31-896a-44bce05f25ff' User entered 'No (N)'	System	17 Aug 2020 23:30:45
	System	17 Aug 2020 23:30:45

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:30:42', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '3b4b4d34-612d-4b31-896a-44bce05f25ff' User entered '17 Aug 2020 18:30'	System	17 Aug 2020 23:30:45
	System	17 Aug 2020 23:30:45

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 3'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:34:41', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '33f4c005-27ae-4b08-985e-2ecea776f9e0' User entered 'Yes (Y)'	System	18 Aug 2020 23:35:22
	System	18 Aug 2020 23:35:22

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:35:10', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '33f4c005-27ae-4b08-985e-2ecce776f9e0' User entered '98.8'	System	18 Aug 2020 23:35:22
	System	18 Aug 2020 23:35:22

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:35:14', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '33f4c005-27ae-4b08-985e-2ecce776f9e0'	System	18 Aug 2020 23:35:22
User entered 'No (N)'	System	18 Aug 2020 23:35:22

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:35:19', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '33f4c005-27ae-4b08-985e-2ecce776f9e0'	System	18 Aug 2020 23:35:22
User entered '18 Aug 2020 18:35'	System	18 Aug 2020 23:35:22

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 4'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:05:02', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '20ce6934-5e03-467e-a3b0-b2108cb3c49b' User entered 'Yes (Y)'	System	20 Aug 2020 01:05:24
	System	20 Aug 2020 01:05:24

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:05:10', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '20ce6934-5e03-467e-a3b0-b2108cb3c49b' User entered '98.2'	System	20 Aug 2020 01:05:24
	System	20 Aug 2020 01:05:24

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:05:17', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '20ce6934-5e03-467e-a3b0-b2108cb3c49b' User entered 'No (N)'	System	20 Aug 2020 01:05:24
	System	20 Aug 2020 01:05:24

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:05:21', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '20ce6934-5e03-467e-a3b0-b2108cb3c49b' User entered '19 Aug 2020 20:05'	System	20 Aug 2020 01:05:24
	System	20 Aug 2020 01:05:24

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 5'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:29:14', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'de9991d9-5c18-4d16-88a5-dfe13841431e' User entered 'Yes (Y)'	System	20 Aug 2020 22:30:04
	System	20 Aug 2020 22:30:04

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:29:27', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'de9991d9-5c18-4d16-88a5-dfe13841431e' User entered '97.1'	System	20 Aug 2020 22:30:04
	System	20 Aug 2020 22:30:04

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:29:40', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'de9991d9-5c18-4d16-88a5-dfe13841431e' User entered 'Yes (Y)'	System	20 Aug 2020 22:30:04
	System	20 Aug 2020 22:30:04

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirm subject took Naproxen for muscle aches' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 09:57:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 22:52:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:29:48', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'de9991d9-5c18-4d16-88a5-dfe13841431e'	System	20 Aug 2020 22:30:04
User entered '1'	System	20 Aug 2020 22:30:04

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:29:48', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'de9991d9-5c18-4d16-88a5-dfe13841431e' User entered '0'	System	20 Aug 2020 22:30:04
	System	20 Aug 2020 22:30:04

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:29:58', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'de9991d9-5c18-4d16-88a5-dfe13841431e' User entered '20 Aug 2020 17:29'	System	20 Aug 2020 22:30:04
	System	20 Aug 2020 22:30:04

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 6'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:07', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c6b37cdd-369b-4cb7-8085-99649a7fa02b' User entered 'Yes (Y)'	System	21 Aug 2020 23:04:36
	System	21 Aug 2020 23:04:36

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:21', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c6b37cdd-369b-4cb7-8085-99649a7fa02b' User entered '98.4'	System	21 Aug 2020 23:04:36
	System	21 Aug 2020 23:04:36

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:26', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c6b37cdd-369b-4cb7-8085-99649a7fa02b'	System	21 Aug 2020 23:04:36
User entered 'No (N)'	System	21 Aug 2020 23:04:36

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:31', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c6b37cdd-369b-4cb7-8085-99649a7fa02b' User entered '21 Aug 2020 18:04'	System	21 Aug 2020 23:04:36
	System	21 Aug 2020 23:04:36

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 7'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:56:53', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'acc4c8a7-88f5-4d0a-bf56-bf5a4c3c0272'	System	23 Aug 2020 01:57:25
User entered 'Yes (Y)'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:03', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'acc4c8a7-88f5-4d0a-bf56-bf5a4c3c0272' User entered '97.9'	System	23 Aug 2020 01:57:25
	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:09', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'acc4c8a7-88f5-4d0a-bf56-bf5a4c3c0272'	System	23 Aug 2020 01:57:25
User entered 'Yes (Y)'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirm subject took Naproxen for headache' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 09:58:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 22:52:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:15', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'acc4c8a7-88f5-4d0a-bf56-bf5a4c3c0272'	System	23 Aug 2020 01:57:25
User entered '1'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:15', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'acc4c8a7-88f5-4d0a-bf56-bf5a4c3c0272' User entered '0'	System	23 Aug 2020 01:57:25
	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:21', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'acc4c8a7-88f5-4d0a-bf56-bf5a4c3c0272'	System	23 Aug 2020 01:57:25
User entered '22 Aug 2020 20:57'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	23 Aug 2020 01:57:25
User entered 'Day 8'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:57:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-23T18:07:44', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a1f219a3-e364-4a36-afc0-5e617b68a256' User entered 'Yes (Y)'	System	23 Aug 2020 23:08:26
	System	23 Aug 2020 23:08:26

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:57:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-23T18:07:53', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a1f219a3-c364-4a36-afc0-5e617b68a256' User entered '97.7'	System	23 Aug 2020 23:08:26
	System	23 Aug 2020 23:08:26

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-23T18:08:20', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a1f219a3-e364-4a36-afc0-5e617b68a256'	System	23 Aug 2020 23:08:26
User entered 'No (N)'	System	23 Aug 2020 23:08:26

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-23T18:08:24', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a1f219a3-c364-4a36-afc0-5e617b68a256'	System	23 Aug 2020 23:08:26
User entered '23 Aug 2020 18:08'	System	23 Aug 2020 23:08:26

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '23 Aug 2020 12:00'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:17:03', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '99017831-9ef8-470f-89a6-7f342acf47c6' User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 17:17:29
	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:17:07', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '99017831-9ef8-470f-89a6-7f342acf47c6' User entered 'No (N)'	System	16 Aug 2020 17:17:29
	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:17:10', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '99017831-9ef8-470f-89a6-7f342acf47c6' User entered 'No (N)'	System	16 Aug 2020 17:17:29
	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:17:19', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '99017831-9ef8-470f-89a6-7f342acf47c6'	System	16 Aug 2020 17:17:29
User entered 'None (1)'	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:17:26', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '99017831-9ef8-470f-89a6-7f342acf47c6' User entered '16 Aug 2020 12:17'	System	16 Aug 2020 17:17:29
	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 11:55'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 14:25'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:25:10', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b8700191-05db-4441-b8ad-60c4e690e4b3'	System	17 Aug 2020 13:25:42
User entered 'None (1)'	System	17 Aug 2020 13:25:42

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:25:13', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b8700191-05db-4441-b8ad-60c4e690e4b3'	System	17 Aug 2020 13:25:42
User entered 'No (N)'	System	17 Aug 2020 13:25:42

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:25:16', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b8700191-05db-4441-b8ad-60c4e690e4b3'	System	17 Aug 2020 13:25:42
User entered 'No (N)'	System	17 Aug 2020 13:25:42

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:25:24', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b8700191-05db-4441-b8ad-60c4e690e4b3'	System	17 Aug 2020 13:25:42
User entered 'None (1)'	System	17 Aug 2020 13:25:42

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:25:38', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b8700191-05db-4441-b8ad-60c4e690e4b3'	System	17 Aug 2020 13:25:42
User entered '17 Aug 2020 08:25'	System	17 Aug 2020 13:25:42

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 15:20'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 2'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:16:58', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '8ed2ef37-1b2b-4a95-a160-0e0562bb819d' User entered 'None (1)'	System	17 Aug 2020 23:17:17
	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:17:01', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '8ed2ef37-1b2b-4a95-a160-0e0562bb819d' User entered 'No (N)'	System	17 Aug 2020 23:17:17
	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:17:05', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '8ed2ef37-1b2b-4a95-a160-0e0562bb819d' User entered 'No (N)'	System	17 Aug 2020 23:17:17
	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:17:09', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '8ed2ef37-1b2b-4a95-a160-0e0562bb819d' User entered 'None (1)'	System	17 Aug 2020 23:17:17
	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:17:14', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '8ed2ef37-1b2b-4a95-a160-0e0562bb819d' User entered '17 Aug 2020 18:17'	System	17 Aug 2020 23:17:17
	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 3'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:29:53', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c997b6de-ad66-4a22-bc4f-4b321af5a020'	System	18 Aug 2020 23:30:21
User entered 'None (1)'	System	18 Aug 2020 23:30:21

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:29:56', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c997b6de-ad66-4a22-bc4f-4b321af5a020'	System	18 Aug 2020 23:30:21
User entered 'No (N)'	System	18 Aug 2020 23:30:21

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:29:58', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c997b6de-ad66-4a22-bc4f-4b321af5a020' User entered 'No (N)'	System	18 Aug 2020 23:30:21
	System	18 Aug 2020 23:30:21

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:11', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c997b6de-ad66-4a22-bc4f-4b321af5a020' User entered 'None (1)'	System	18 Aug 2020 23:30:21
	System	18 Aug 2020 23:30:21

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:18', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c997b6de-ad66-4a22-bc4f-4b321af5a020' User entered '18 Aug 2020 18:30'	System	18 Aug 2020 23:30:21
	System	18 Aug 2020 23:30:21

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 4'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:01:49', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'db0835c2-e74e-4e47-b692-97100266739b' User entered 'None (1)'	System	20 Aug 2020 01:02:17
	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:02:05', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'db0835c2-e74e-4e47-b692-97100266739b' User entered 'No (N)'	System	20 Aug 2020 01:02:17
	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:02:08', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'db0835c2-e74e-4e47-b692-97100266739b' User entered 'No (N)'	System	20 Aug 2020 01:02:17
	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:02:10', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'db0835c2-e74e-4e47-b692-97100266739b' User entered 'None (1)'	System	20 Aug 2020 01:02:17
	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:02:15', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'db0835c2-e74e-4e47-b692-97100266739b' User entered '19 Aug 2020 20:02'	System	20 Aug 2020 01:02:17
	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 5'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:06:56', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cc1c8066-4c7b-4fac-90c4-3427c1e45163'	System	20 Aug 2020 22:07:13
User entered 'None (1)'	System	20 Aug 2020 22:07:13

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:06:59', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cc1c8066-4c7b-4fac-90c4-3427c1e45163' User entered 'No (N)'	System	20 Aug 2020 22:07:13
	System	20 Aug 2020 22:07:13

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:07:03', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cc1c8066-4c7b-4fac-90c4-3427c1e45163' User entered 'No (N)'	System	20 Aug 2020 22:07:13
	System	20 Aug 2020 22:07:13

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:07:06', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cc1c8066-4c7b-4fac-90c4-3427c1e45163' User entered 'None (1)'	System	20 Aug 2020 22:07:13
	System	20 Aug 2020 22:07:13

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:07:09', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cc1c8066-4c7b-4fac-90c4-3427c1e45163' User entered '20 Aug 2020 17:07'	System	20 Aug 2020 22:07:13
	System	20 Aug 2020 22:07:13

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 6'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:37', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'f5753282-96c2-4507-868a-3ddbc2bba72d' User entered 'None (1)'	System	21 Aug 2020 23:04:53
	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:40', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'f5753282-96c2-4507-868a-3ddbc2bba72d' User entered 'No (N)'	System	21 Aug 2020 23:04:53
	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:44', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'f5753282-96c2-4507-868a-3ddbc2bba72d' User entered 'No (N)'	System	21 Aug 2020 23:04:53
	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:48', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'f5753282-96c2-4507-868a-3ddbc2bba72d' User entered 'None (1)'	System	21 Aug 2020 23:04:53
	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:51', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'f5753282-96c2-4507-868a-3ddbc2bba72d' User entered '21 Aug 2020 18:04'	System	21 Aug 2020 23:04:53
	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 7'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:56:21', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd4860b8b-80e6-4177-b209-ebf91a4fdd27'	System	23 Aug 2020 01:56:39
User entered 'None (1)'	System	23 Aug 2020 01:56:39

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:56:24', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd4860b8b-80e6-4177-b209-ebf91a4fdd27'	System	23 Aug 2020 01:56:39
User entered 'No (N)'	System	23 Aug 2020 01:56:39

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:56:27', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd4860b8b-80e6-4177-b209-ebf91a4fdd27'	System	23 Aug 2020 01:56:39
User entered 'No (N)'	System	23 Aug 2020 01:56:39

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:56:30', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd4860b8b-80e6-4177-b209-ebf91a4fdd27'	System	23 Aug 2020 01:56:39
User entered 'None (1)'	System	23 Aug 2020 01:56:39

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:56:36', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd4860b8b-80e6-4177-b209-ebf91a4fdd27'	System	23 Aug 2020 01:56:39
User entered '22 Aug 2020 20:56'	System	23 Aug 2020 01:56:39

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:17:43', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fb9ae893-e74e-41aa-9887-29447f830c8f' User entered 'None (0)'	System	16 Aug 2020 17:18:27
	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:17:52', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fb9ae893-e74e-41aa-9887-29447f830c8f' User entered 'None (0)'	System	16 Aug 2020 17:18:27
	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:17:59', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fb9ae893-e74e-41aa-9887-29447f830c8f' User entered 'None (0)'	System	16 Aug 2020 17:18:27
	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:18:07', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fb9ae893-e74e-41aa-9887-29447f830c8f' User entered 'None (0)'	System	16 Aug 2020 17:18:27
	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:18:10', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fb9ae893-e74e-41aa-9887-29447f830c8f' User entered 'None (0)'	System	16 Aug 2020 17:18:27
	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:18:17', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fb9ae893-e74e-41aa-9887-29447f830c8f' User entered 'None (0)'	System	16 Aug 2020 17:18:27
	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:18:21', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fb9ae893-e74e-41aa-9887-29447f830c8f' User entered 'No (N)'	System	16 Aug 2020 17:18:27
	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-16T12:18:25', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fb9ae893-e74e-41aa-9887-29447f830c8f' User entered '16 Aug 2020 12:18'	System	16 Aug 2020 17:18:27
	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 11:55'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 14:25'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:25:52', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ead540ea-92ef-42cb-9619-20a6e7b794bf' User entered 'None (0)'	System	17 Aug 2020 13:26:26
	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:25:55', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ead540ea-92ef-42cb-9619-20a6e7b794bf' User entered 'None (0)'	System	17 Aug 2020 13:26:26
	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ead540ea-92ef-42cb-9619-20a6e7b794bf' User entered 'None (0)'	System	17 Aug 2020 13:26:26
	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:04', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ead540ea-92ef-42cb-9619-20a6e7b794bf' User entered 'None (0)'	System	17 Aug 2020 13:26:26
	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:07', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ead540ea-92ef-42cb-9619-20a6e7b794bf' User entered 'None (0)'	System	17 Aug 2020 13:26:26
	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:09', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ead540ea-92ef-42cb-9619-20a6e7b794bf' User entered 'None (0)'	System	17 Aug 2020 13:26:26
	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:13', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ead540ea-92ef-42cb-9619-20a6e7b794bf' User entered 'No (N)'	System	17 Aug 2020 13:26:26
	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T08:26:24', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ead540ea-92ef-42cb-9619-20a6e7b794bf' User entered '17 Aug 2020 08:26'	System	17 Aug 2020 13:26:26
	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '16 Aug 2020 15:20'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 2'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:17:46', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9e3025e1-e575-4ddc-a801-b2306ec50c87' User entered 'None (0)'	System	17 Aug 2020 23:18:20
	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:17:50', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9e3025e1-e575-4ddc-a801-b2306ec50c87' User entered 'None (0)'	System	17 Aug 2020 23:18:20
	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:17:54', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9e3025e1-e575-4ddc-a801-b2306ec50c87' User entered 'None (0)'	System	17 Aug 2020 23:18:20
	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:17:58', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9e3025e1-e575-4ddc-a801-b2306ec50c87' User entered 'None (0)'	System	17 Aug 2020 23:18:20
	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:18:01', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9e3025e1-e575-4ddc-a801-b2306ec50c87' User entered 'None (0)'	System	17 Aug 2020 23:18:20
	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:18:05', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9e3025e1-e575-4ddc-a801-b2306ec50c87' User entered 'None (0)'	System	17 Aug 2020 23:18:20
	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:18:12', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9e3025e1-e575-4ddc-a801-b2306ec50c87' User entered 'No (N)'	System	17 Aug 2020 23:18:20
	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-17T18:18:18', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9e3025e1-e575-4ddc-a801-b2306ec50c87' User entered '17 Aug 2020 18:18'	System	17 Aug 2020 23:18:20
	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 3'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:33', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '888fd289-1009-4256-9532-79cba35e2425' User entered 'None (0)'	System	18 Aug 2020 23:31:12
	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:37', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '888fd289-1009-4256-9532-79cba35e2425' User entered 'None (0)'	System	18 Aug 2020 23:31:12
	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:42', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '888fd289-1009-4256-9532-79cba35e2425'	System	18 Aug 2020 23:31:12
User entered 'No interference with activity (1)'	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:50', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '888fd289-1009-4256-9532-79cba35e2425'	System	18 Aug 2020 23:31:12
User entered 'No interference with activity (1)'	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:52', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '888fd289-1009-4256-9532-79cba35e2425' User entered 'None (0)'	System	18 Aug 2020 23:31:12
	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:55', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '888fd289-1009-4256-9532-79cba35e2425' User entered 'None (0)'	System	18 Aug 2020 23:31:12
	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:30:59', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '888fd289-1009-4256-9532-79cba35e2425'	System	18 Aug 2020 23:31:12
User entered 'No (N)'	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-18T18:31:10', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '888fd289-1009-4256-9532-79cba35e2425' User entered '18 Aug 2020 18:31'	System	18 Aug 2020 23:31:12
	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 4'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:00:57', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'e8bec718-4cf8-425c-9fdc-ed750317d173' User entered 'None (0)'	System	20 Aug 2020 01:01:19
	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:00:59', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'e8bec718-4cf8-425c-9fdc-ed750317d173' User entered 'None (0)'	System	20 Aug 2020 01:01:19
	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:01:01', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'e8bec718-4cf8-425c-9fdc-ed750317d173' User entered 'None (0)'	System	20 Aug 2020 01:01:19
	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:01:04', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'e8bec718-4cf8-425c-9fdc-ed750317d173' User entered 'None (0)'	System	20 Aug 2020 01:01:19
	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:01:06', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'e8bec718-4cf8-425c-9fdc-ed750317d173' User entered 'None (0)'	System	20 Aug 2020 01:01:19
	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:01:09', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'e8bec718-4cf8-425c-9fdc-ed750317d173' User entered 'None (0)'	System	20 Aug 2020 01:01:19
	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:01:13', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'e8bec718-4cf8-425c-9fdc-ed750317d173' User entered 'No (N)'	System	20 Aug 2020 01:01:19
	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-19T20:01:16', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'e8bec718-4cf8-425c-9fdc-ed750317d173' User entered '19 Aug 2020 20:01'	System	20 Aug 2020 01:01:19
	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 5'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:05:41', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a23f4546-e509-4996-9900-c41c0552e597' User entered 'None (0)'	System	20 Aug 2020 22:06:16
	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:05:49', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a23f4546-e509-4996-9900-c41c0552e597' User entered 'None (0)'	System	20 Aug 2020 22:06:16
	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:05:56', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a23f4546-e509-4996-9900-c41c0552e597'	System	20 Aug 2020 22:06:16
User entered 'No interference with activity (1)'	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a23f4546-e509-4996-9900-c41c0552e597' User entered 'None (0)'	System	20 Aug 2020 22:06:16
	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:06:04', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a23f4546-e509-4996-9900-c41c0552e597'	System	20 Aug 2020 22:06:16
User entered 'None (0)'	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:06:07', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a23f4546-e509-4996-9900-c41c0552e597'	System	20 Aug 2020 22:06:16
User entered 'None (0)'	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:06:11', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a23f4546-e509-4996-9900-c41c0552e597'	System	20 Aug 2020 22:06:16
User entered 'No (N)'	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-20T17:06:14', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a23f4546-e509-4996-9900-c41c0552e597' User entered '20 Aug 2020 17:06'	System	20 Aug 2020 22:06:16
	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 6'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:04:59', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1de347fd-18af-4129-a5fe-98db0d60adc4' User entered 'None (0)'	System	21 Aug 2020 23:05:29
	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:05:03', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1de347fd-18af-4129-a5fe-98db0d60adc4' User entered 'None (0)'	System	21 Aug 2020 23:05:29
	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:05:05', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1de347fd-18af-4129-a5fe-98db0d60adc4' User entered 'None (0)'	System	21 Aug 2020 23:05:29
	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:05:10', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1de347fd-18af-4129-a5fe-98db0d60adc4' User entered 'None (0)'	System	21 Aug 2020 23:05:29
	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:05:12', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1de347fd-18af-4129-a5fe-98db0d60adc4' User entered 'None (0)'	System	21 Aug 2020 23:05:29
	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:05:15', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1de347fd-18af-4129-a5fe-98db0d60adc4' User entered 'None (0)'	System	21 Aug 2020 23:05:29
	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:05:22', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1de347fd-18af-4129-a5fe-98db0d60adc4' User entered 'No (N)'	System	21 Aug 2020 23:05:29
	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-21T18:05:25', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1de347fd-18af-4129-a5fe-98db0d60adc4' User entered '21 Aug 2020 18:05'	System	21 Aug 2020 23:05:29
	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 7'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:29', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cbe5a784-f743-4a8a-ae44-a0833276489f'	System	23 Aug 2020 01:58:08
User entered 'No interference with activity (1)'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:33', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cbe5a784-f743-4a8a-ae44-a0833276489f' User entered 'None (0)'	System	23 Aug 2020 01:58:08
	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:41', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cbe5a784-f743-4a8a-ae44-a0833276489f' User entered 'None (0)'	System	23 Aug 2020 01:58:08
	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:46', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cbe5a784-f743-4a8a-ae44-a0833276489f' User entered 'None (0)'	System	23 Aug 2020 01:58:08
	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:49', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cbe5a784-f743-4a8a-ae44-a0833276489f' User entered 'None (0)'	System	23 Aug 2020 01:58:08
	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:52', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cbe5a784-f743-4a8a-ae44-a0833276489f' User entered 'None (0)'	System	23 Aug 2020 01:58:08
	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:57:59', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cbe5a784-f743-4a8a-ae44-a0833276489f' User entered 'No (N)'	System	23 Aug 2020 01:58:08
	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-22T20:58:03', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'cbe5a784-f743-4a8a-ae44-a0833276489f' User entered '22 Aug 2020 20:58'	System	23 Aug 2020 01:58:08
	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	23 Aug 2020 01:58:08
User entered 'Day 8'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-23T18:05:54', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b0761596-78ad-4053-97fb-1397dcf53de3' User entered 'None (0)'	System	23 Aug 2020 23:06:04
	System	23 Aug 2020 23:06:04

US3592196

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-23T18:06:02', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b0761596-78ad-4053-97fb-1397dcf53de3'	System	23 Aug 2020 23:06:04
User entered '23 Aug 2020 18:06'	System	23 Aug 2020 23:06:04

US3592196

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '23 Aug 2020 12:00'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	23 Aug 2020 01:57:25
User entered 'Day 8'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-23T18:05:38', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ccd9bae9-36e0-4bc1-b483-db24e595af4b' User entered 'No (N)'	System	23 Aug 2020 23:05:49
	System	23 Aug 2020 23:05:49

US3592196

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-08-23T18:05:47', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'ccd9bae9-36e0-4bc1-b483-db24e595af4b' User entered '23 Aug 2020 18:05'	System	23 Aug 2020 23:05:49
	System	23 Aug 2020 23:05:49

US3592196

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '23 Aug 2020 12:00'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:57:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 01:57:25

US3592196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 21:49:22

US3592196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:14
User entered '24 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 21:49:22

US3592196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 21:49:22

US3592196

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:14
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 21:49:22

US3592196

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 21:49:30

US3592196

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'l'	System	08 Sep 2020 21:49:30

US3592196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 21:50:35

US3592196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:34
User entered '30 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 21:50:35

US3592196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 21:50:35

US3592196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:34
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 21:50:35

US3592196

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:07:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 21:50:47

US3592196

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:18:15
User entered 'l'	System	08 Sep 2020 21:50:47

US3592196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:58:21
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:09:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 21:53:56

US3592196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:58:21
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:09:35
User entered '7 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 21:53:56

US3592196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:58:21
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:09:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 21:53:56

US3592196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:58:21
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:09:35
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 21:53:56

US3592196

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:58:21
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:09:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 21:54:11

US3592196

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:58:21
User entered 'I'	System	08 Sep 2020 21:54:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:10:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Sep 2020 16:40:03

US3592196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:10:07
User entered '13 Sep 2020'	(b) (4), (b) (6)	13 Sep 2020 16:40:03

US3592196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:10:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Sep 2020 16:40:03

US3592196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'VISIT2'	System	13 Sep 2020 16:40:03

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User accepted default value 'Pre-Dose (PREDOSE)'		13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered '13 Sep 2020'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered '09:50'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered '13 Sep 2020 09:50'	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered '98.1' F	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered '88'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'bpm'	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered '16'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'breaths/min'	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered '104'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'mmHg'	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered '68'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'mmHg'	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered 'No (N)'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:05
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Sep 2020 16:44:18

US3592196

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:09
User entered '13 Sep 2020'	(b) (4), (b) (6)	13 Sep 2020 16:44:18

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:16
User entered 'No (N)'	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
Query 'Subject does not have any source indicating COVID 19 Positive. Please provide or update this response.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:25:42
User opened query 'Subject does not have any source indicating COVID 19 Positive. Please provide or update this response.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 17:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 17:11:16
User closed query 'Per CDM: Please complete the Covid-19 assessment page, AE page and Dosing discontinuation to record covid-19 diagnosis.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:03:23
Query 'Per CDM: Please complete the Covid-19 assessment page, AE page and Dosing discontinuation to record covid-19 diagnosis.' answered with 'added as an AE' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 19:49:21
User opened query 'Per CDM: Please complete the Covid-19 assessment page, AE page and Dosing discontinuation to record covid-19 diagnosis.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 07:43:04
User entered 'Confirmed COVID-19 (COVID)'	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

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 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:16
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:16
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:16
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:16
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
DataPoint Verified.		12 Jan 2021 17:11:16
User entered empty.	System	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Sep 2020 16:43:05

US3592196

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:21
User entered '13 Sep 2020'	(b) (4), (b) (6)	13 Sep 2020 16:43:05

US3592196

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:21
User entered '10:17'	(b) (4), (b) (6)	13 Sep 2020 16:43:05

US3592196

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered '13 Sep 2020 10:17'	System	13 Sep 2020 16:43:05

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:25
User entered '13 Sep 2020'	(b) (4), (b) (6)	13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:25
User entered '10:19'	(b) (4), (b) (6)	13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered '13 Sep 2020 10:19'	System	13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:25
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered empty.	System	13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Sep 2020 16:43:54

US3592196

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'l'	System	13 Sep 2020 16:43:54

US3592196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:48:09

US3592196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:54
User entered '22 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 18:48:09

US3592196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 18:48:09

US3592196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:11:54
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:48:09

US3592196

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:03:27
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:27:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 18:48:13

US3592196

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'l'	System	02 Oct 2020 18:48:13

US3592196

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:56:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:49:38

US3592196

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:56:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:17
User entered '29 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 18:49:38

US3592196

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:56:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 18:49:38

US3592196

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:56:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:17
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:49:38

US3592196

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 15:56:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:49:43

US3592196

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'l'	System	02 Oct 2020 18:49:43

US3592196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:40
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 13:28:47
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'visit 3 immunogenicity completed ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:02:32
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 12:37:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 20:19:38

US3592196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:40
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 20:19:38

US3592196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 20:19:38

US3592196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:40
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 20:19:38

US3592196

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:12:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 20:19:44

US3592196

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'l'	System	06 Oct 2020 20:19:44

US3592196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:10:42

US3592196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:00
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 23:11:30
User entered '13 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 23:10:42

US3592196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Nov 2020 23:10:42

US3592196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'VISIT3'	System	17 Nov 2020 23:10:42

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Nov 2020 23:11:30
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Nov 2020 23:11:30
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Nov 2020 23:11:18
User entered '13 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered '11:37'	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered '13 Oct 2020 11:37'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered '98.3' F	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered '77'	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'bpm'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered '16'	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'breaths/min'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered '96'	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'mmHg'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:34
User entered '64'	(b) (4), (b) (6)	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'mmHg'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01

US3592196

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:41
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 23:11:45

US3592196

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:13:41
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 23:11:45

US3592196

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:17:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:11:58

US3592196

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:17:58
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Nov 2020 23:12:03
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		17 Nov 2020 23:12:03
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 23:12:03
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Nov 2020 23:11:58
User entered '13 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 23:11:58

US3592196

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:17:58
User entered '11:53'	(b) (4), (b) (6)	17 Nov 2020 23:11:58

US3592196

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered '13 Oct 2020 11:53'	System	17 Nov 2020 23:12:03
User entered '13 Nov 2020 11:53'	System	17 Nov 2020 23:11:58

US3592196

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	19 Feb 2021 16:42:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:12:07

US3592196

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'l'	System	17 Nov 2020 23:12:07

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 64'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-16T17:31:41', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9704f48b-1abc-4270-ac8a-bbf01a1d7984' User entered 'No (N)'	System	16 Oct 2020 22:32:03
	System	16 Oct 2020 22:32:03

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-16T17:31:49', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9704f48b-1abc-4270-ac8a-bbf01a1d7984'	System	16 Oct 2020 22:32:03
User entered 'No (N)'	System	16 Oct 2020 22:32:03

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-16T17:31:57', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9704f48b-1abc-4270-ac8a-bbf01a1d7984' User entered '16 Oct 2020 17:31:57'	System	16 Oct 2020 22:32:03
	System	16 Oct 2020 22:32:03

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered '16 Oct 2020 00:01'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered '20 Oct 2020 23:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 71'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-24T14:22:59', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9f13a549-5679-459e-9680-15d4bd31a8d6' User entered 'No (N)'	System	24 Oct 2020 19:23:18
	System	24 Oct 2020 19:23:18

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-24T14:23:06', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9f13a549-5679-459e-9680-15d4bd31a8d6'	System	24 Oct 2020 19:23:18
User entered 'No (N)'	System	24 Oct 2020 19:23:18

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-24T14:23:15', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9f13a549-5679-459e-9680-15d4bd31a8d6' User entered '24 Oct 2020 14:23:15'	System	24 Oct 2020 19:23:18
	System	24 Oct 2020 19:23:18

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered '23 Oct 2020 00:01'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered '27 Oct 2020 23:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 78'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-31T04:47:19', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a6792b21-59d1-432e-a1e5-86bfd7ac6962'	System	31 Oct 2020 09:47:37
User entered 'No (N)'	System	31 Oct 2020 09:47:37

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-31T04:47:25', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a6792b21-59d1-432e-a1e5-86bfd7ac6962'	System	31 Oct 2020 09:47:37
User entered 'No (N)'	System	31 Oct 2020 09:47:37

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-10-31T04:47:33', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'a6792b21-59d1-432e-a1e5-86bfd7ac6962' User entered '31 Oct 2020 04:47:33'	System	31 Oct 2020 09:47:37
	System	31 Oct 2020 09:47:37

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered '30 Oct 2020 00:01'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered '03 Nov 2020 23:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered 'Day 92'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-13T09:04:49', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1fd2f4ab-6337-4dc2-b9c4-ca106280cca0' User entered 'No (N)'	System	13 Nov 2020 15:05:05
	System	13 Nov 2020 15:05:05

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-13T09:04:54', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1fd2f4ab-6337-4dc2-b9c4-ca106280cca0'	System	13 Nov 2020 15:05:05
User entered 'No (N)'	System	13 Nov 2020 15:05:05

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-13T09:05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1fd2f4ab-6337-4dc2-b9c4-ca106280cca0' User entered '13 Nov 2020 09:05:00'	System	13 Nov 2020 15:05:05
	System	13 Nov 2020 15:05:05

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered '13 Nov 2020 00:01'	System	16 Aug 2020 16:40:55

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:39:58
Data entry locked.	System	16 Aug 2020 16:40:55
User entered '17 Nov 2020 23:59'	System	16 Aug 2020 16:40:55

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-19T09:31:44', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '83f9fa5d-b81d-4c11-b2dd-b36fc646b041' User entered 'No (N)'	System	19 Nov 2020 15:32:00
	System	19 Nov 2020 15:32:00

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-19T09:31:49', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '83f9fa5d-b81d-4c11-b2dd-b36fc646b041' User entered 'No (N)'	System	19 Nov 2020 15:32:00
	System	19 Nov 2020 15:32:00

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-19T09:31:58', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '83f9fa5d-b81d-4c11-b2dd-b36fc646b041' User entered '19 Nov 2020 09:31:58'	System	19 Nov 2020 15:32:00
	System	19 Nov 2020 15:32:00

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-25T08:18:38', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd43a4005-0318-4349-bad1-293e07caebd1'	System	25 Nov 2020 14:19:03
User entered 'No (N)'	System	25 Nov 2020 14:19:03

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-25T08:18:34', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd43a4005-0318-4349-bad1-293e07caebd1'	System	25 Nov 2020 14:19:03
User entered 'Yes (Y)'	System	25 Nov 2020 14:19:03

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Please 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-25T08:18:43', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd43a4005-0318-4349-bad1-293e07caebd1'	System	25 Nov 2020 14:19:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 14:19:03

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-11-25T08:18:54', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd43a4005-0318-4349-bad1-293e07caebd1' User entered '25 Nov 2020 08:18:54'	System	25 Nov 2020 14:19:03
	System	25 Nov 2020 14:19:03

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-01T16:36:56', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '4dde524f-cfe1-4b53-a004-1d99a8da81f2'	System	01 Dec 2020 22:37:28
User entered 'No (N)'	System	01 Dec 2020 22:37:28

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-01T16:37:18', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '4dde524f-cfe1-4b53-a004-1d99a8da81f2'	System	01 Dec 2020 22:37:28
User entered 'No (N)'	System	01 Dec 2020 22:37:28

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-01T16:37:26', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '4dde524f-cfe1-4b53-a004-1d99a8da81f2' User entered '01 Dec 2020 16:37:26'	System	01 Dec 2020 22:37:28
	System	01 Dec 2020 22:37:28

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-08T18:49:23', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b71d186b-06af-4f9f-baf0-880093718263' User entered 'No (N)'	System	09 Dec 2020 00:49:44
	System	09 Dec 2020 00:49:44

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-08T18:49:30', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b71d186b-06af-4f9f-baf0-880093718263'	System	09 Dec 2020 00:49:44
User entered 'No (N)'	System	09 Dec 2020 00:49:44

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-08T18:49:41', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'b71d186b-06af-4f9f-baf0-880093718263' User entered '08 Dec 2020 18:49:41'	System	09 Dec 2020 00:49:44
	System	09 Dec 2020 00:49:44

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-15T11:28:54', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '55800d27-b624-4956-94b0-98059b9be872' User entered 'No (N)'	System	15 Dec 2020 17:29:08
	System	15 Dec 2020 17:29:08

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-15T11:29:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '55800d27-b624-4956-94b0-98059b9be872'	System	15 Dec 2020 17:29:08
User entered 'No (N)'	System	15 Dec 2020 17:29:08

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-15T11:29:04', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '55800d27-b624-4956-94b0-98059b9be872' User entered '15 Dec 2020 11:29:04'	System	15 Dec 2020 17:29:08

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-22T07:39:54', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1f6714c5-1445-4133-acbd-2492e79090bf' User entered 'No (N)'	System	22 Dec 2020 13:40:07
	System	22 Dec 2020 13:40:07

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-22T07:39:59', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1f6714c5-1445-4133-acbd-2492e79090bf' User entered 'No (N)'	System	22 Dec 2020 13:40:07
	System	22 Dec 2020 13:40:07

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-22T07:40:02', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1f6714c5-1445-4133-acbd-2492e79090bf' User entered '22 Dec 2020 07:40:02'	System	22 Dec 2020 13:40:07
	System	22 Dec 2020 13:40:07

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-29T07:11:41', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '17d7d17d-4193-437c-a6be-d251a98fc5e2' User entered 'No (N)'	System	29 Dec 2020 13:11:56
	System	29 Dec 2020 13:11:56

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-29T07:11:47', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '17d7d17d-4193-437c-a6be-d251a98fc5e2' User entered 'No (N)'	System	29 Dec 2020 13:11:56
	System	29 Dec 2020 13:11:56

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2020-12-29T07:11:52', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '17d7d17d-4193-437c-a6be-d251a98fc5e2' User entered '29 Dec 2020 07:11:52'	System	29 Dec 2020 13:11:56
	System	29 Dec 2020 13:11:56

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-05T08:26:05', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '79adb9d8-938f-4a4e-8b74-8dff123fd57c' User entered 'No (N)'	System	05 Jan 2021 14:26:21

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-05T08:26:13', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '79adb9d8-938f-4a4e-8b74-8dff123fd57c'	System	05 Jan 2021 14:26:21
User entered 'No (N)'	System	05 Jan 2021 14:26:21

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-05T08:26:18', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '79adb9d8-938f-4a4e-8b74-8dff123fd57c' User entered '05 Jan 2021 08:26:18'	System	05 Jan 2021 14:26:21

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-12T08:32:35', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9aad23f9-db91-48a9-bb59-460280093bf2' User entered 'No (N)'	System	12 Jan 2021 14:32:48

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-12T08:32:41', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9aad23f9-db91-48a9-bb59-460280093bf2' User entered 'No (N)'	System	12 Jan 2021 14:32:48
	System	12 Jan 2021 14:32:48

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-12T08:32:45', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9aad23f9-db91-48a9-bb59-460280093bf2' User entered '12 Jan 2021 08:32:45'	System	12 Jan 2021 14:32:48
	System	12 Jan 2021 14:32:48

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-19T23:01:14', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '445ef3b4-7a9d-410d-8e80-27149b82b5a9' User entered 'No (N)'	System	20 Jan 2021 05:01:40
	System	20 Jan 2021 05:01:40

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-19T23:01:20', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '445ef3b4-7a9d-410d-8e80-27149b82b5a9' User entered 'No (N)'	System	20 Jan 2021 05:01:40

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-19T23:01:30', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '445ef3b4-7a9d-410d-8e80-27149b82b5a9' User entered '19 Jan 2021 23:01:30'	System	20 Jan 2021 05:01:40

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-26T01:20:17', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '68feee96-a0a5-4b8a-8a36-edb323170840' User entered 'No (N)'	System	26 Jan 2021 07:20:29
	System	26 Jan 2021 07:20:29

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-26T01:20:23', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '68feee96-a0a5-4b8a-8a36-edb323170840' User entered 'No (N)'	System	26 Jan 2021 07:20:29
	System	26 Jan 2021 07:20:29

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-01-26T01:20:27', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '68feee96-a0a5-4b8a-8a36-edb323170840' User entered '26 Jan 2021 01:20:27'	System	26 Jan 2021 07:20:29
	System	26 Jan 2021 07:20:29

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-02T09:11:45', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'db8e64ba-6e40-495a-ae17-8188ee837cb7' User entered 'No (N)'	System	02 Feb 2021 15:12:08
	System	02 Feb 2021 15:12:08

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-02T09:11:49', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'db8e64ba-6e40-495a-ae17-8188ee837cb7'	System	02 Feb 2021 15:12:08
User entered 'No (N)'	System	02 Feb 2021 15:12:08

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-02T09:12:03', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'db8e64ba-6e40-495a-ae17-8188ee837cb7'	System	02 Feb 2021 15:12:08
User entered '02 Feb 2021 09:12:03'	System	02 Feb 2021 15:12:08

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-09T18:47:36', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1dd8dc49-4e15-4816-982f-259726d2b0ed' User entered 'No (N)'	System	10 Feb 2021 00:47:47

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-09T18:47:42', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1dd8dc49-4e15-4816-982f-259726d2b0ed' User entered 'No (N)'	System	10 Feb 2021 00:47:47

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-09T18:47:45', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1dd8dc49-4e15-4816-982f-259726d2b0ed' User entered '09 Feb 2021 18:47:45'	System	10 Feb 2021 00:47:47

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-16T10:22:56', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9cdcecb6-a7e1-4cca-912c-1bb73f06f4a1' User entered 'No (N)'	System	16 Feb 2021 16:23:10
	System	16 Feb 2021 16:23:10

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-16T10:23:03', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9cdcecb6-a7e1-4cca-912c-1bb73f06f4a1' User entered 'No (N)'	System	16 Feb 2021 16:23:10

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-16T10:23:07', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9cdcecb6-a7e1-4cca-912c-1bb73f06f4a1' User entered '16 Feb 2021 10:23:07'	System	16 Feb 2021 16:23:10
	System	16 Feb 2021 16:23:10

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-23T09:58:39-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '72d79ba6-7385-436e-8d53-7869f1b699bc' User entered 'No (N)'	System	23 Feb 2021 15:58:55
	System	23 Feb 2021 15:58:55

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-23T09:58:44-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '72d79ba6-7385-436e-8d53-7869f1b699bc'	System	23 Feb 2021 15:58:55
User entered 'No (N)'	System	23 Feb 2021 15:58:55

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-23T09:58:50-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '72d79ba6-7385-436e-8d53-7869f1b699bc'	System	23 Feb 2021 15:58:55
User entered '23 Feb 2021 15:58:50'	System	23 Feb 2021 15:58:55

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-02T10:57:08-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '84ebdfc3-954b-48c8-92f1-f0738839d6c4'	System	02 Mar 2021 16:57:24
User entered 'No (N)'	System	02 Mar 2021 16:57:24

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-02T10:57:15-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '84ebdfc3-954b-48c8-92f1-f0738839d6c4'	System	02 Mar 2021 16:57:24
User entered 'No (N)'	System	02 Mar 2021 16:57:24

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-02T10:57:20-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '84ebdfc3-954b-48c8-92f1-f0738839d6c4' User entered '02 Mar 2021 10:57:20'	System	02 Mar 2021 16:57:24
	System	02 Mar 2021 16:57:24

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-09T10:57:44-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c75270f6-fd87-4019-9ba3-a79e6aa06369'	System	09 Mar 2021 16:58:02
User entered 'No (N)'	System	09 Mar 2021 16:58:02

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-09T10:57:49-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c75270f6-fd87-4019-9ba3-a79e6aa06369'	System	09 Mar 2021 16:58:02
User entered 'No (N)'	System	09 Mar 2021 16:58:02

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-09T10:57:54-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'c75270f6-fd87-4019-9ba3-a79e6aa06369' User entered '09 Mar 2021 10:57:54'	System	09 Mar 2021 16:58:02
	System	09 Mar 2021 16:58:02

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-16T08:07:31-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '74ae1401-ce14-42eb-a9c5-5b98299bfb3c' User entered 'No (N)'	System	16 Mar 2021 13:07:47
	System	16 Mar 2021 13:07:47

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-16T08:07:37-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '74ae1401-ce14-42eb-a9c5-5b98299bfb3c' User entered 'No (N)'	System	16 Mar 2021 13:07:47
	System	16 Mar 2021 13:07:47

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-16T08:07:44-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '74ae1401-ce14-42eb-a9c5-5b98299bfb3c' User entered '16 Mar 2021 08:07:44'	System	16 Mar 2021 13:07:47
	System	16 Mar 2021 13:07:47

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-23T23:51:29-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '61dea87b-49af-4279-b742-cf5e20e37cc6'	System	24 Mar 2021 04:51:41
User entered 'No (N)'	System	24 Mar 2021 04:51:41

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-23T23:51:33-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '61dea87b-49af-4279-b742-cf5e20e37cc6'	System	24 Mar 2021 04:51:41
User entered 'No (N)'	System	24 Mar 2021 04:51:41

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-23T23:51:37-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '61dea87b-49af-4279-b742-cf5e20e37cc6'	System	24 Mar 2021 04:51:41
User entered '23 Mar 2021 23:51:37'	System	24 Mar 2021 04:51:41

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-30T08:02:55-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '7c361af3-b684-43ee-8b88-20420a2b44e9' User entered 'No (N)'	System	30 Mar 2021 13:03:10
	System	30 Mar 2021 13:03:10

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-30T08:03:00-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '7c361af3-b684-43ee-8b88-20420a2b44e9' User entered 'No (N)'	System	30 Mar 2021 13:03:10

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-03-30T08:03:04-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '7c361af3-b684-43ee-8b88-20420a2b44e9' User entered '30 Mar 2021 08:03:04'	System	30 Mar 2021 13:03:10
	System	30 Mar 2021 13:03:10

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-06T10:50:20-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fedfbaea-9728-417f-9370-b155a86f9177'	System	06 Apr 2021 15:50:38
User entered 'No (N)'	System	06 Apr 2021 15:50:38

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-06T10:50:25-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fedfbaea-9728-417f-9370-b155a86f9177'	System	06 Apr 2021 15:50:38
User entered 'No (N)'	System	06 Apr 2021 15:50:38

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-06T10:50:31-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'fedfbaea-9728-417f-9370-b155a86f9177'	System	06 Apr 2021 15:50:38
User entered '06 Apr 2021 10:50:31'	System	06 Apr 2021 15:50:38

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-13T09:37:41-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '82167e8e-cf46-404b-ab97-ab446d1b9787' User entered 'No (N)'	System	13 Apr 2021 14:37:54
	System	13 Apr 2021 14:37:54

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-13T09:37:45-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '82167e8e-cf46-404b-ab97-ab446d1b9787' User entered 'No (N)'	System	13 Apr 2021 14:37:54
	System	13 Apr 2021 14:37:54

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-13T09:37:49-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '82167e8e-cf46-404b-ab97-ab446d1b9787'	System	13 Apr 2021 14:37:54
User entered '13 Apr 2021 09:37:49'	System	13 Apr 2021 14:37:54

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-20T19:45:18-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '7b60108d-5d92-4624-9748-ab3007b39fff' User entered 'No (N)'	System	21 Apr 2021 00:45:31
	System	21 Apr 2021 00:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-20T19:45:23-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '7b60108d-5d92-4624-9748-ab3007b39fff'	System	21 Apr 2021 00:45:31
User entered 'No (N)'	System	21 Apr 2021 00:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-20T19:45:27-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '7b60108d-5d92-4624-9748-ab3007b39fff'	System	21 Apr 2021 00:45:31
User entered '20 Apr 2021 19:45:27'	System	21 Apr 2021 00:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-27T09:13:33-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '2a3cdbe9-fe18-4de6-8145-15c2ee72916a' User entered 'No (N)'	System	27 Apr 2021 14:13:44

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

Have you been exposed to someone with 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 (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-27T09:13:37-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '2a3cdb9-fe18-4de6-8145-15c2ee72916a' User entered 'No (N)'	System	27 Apr 2021 14:13:44

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-04-27T09:13:41-05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '2a3cdbe9-fe18-4de6-8145-15c2ee72916a' User entered '27 Apr 2021 09:13:41'	System	27 Apr 2021 14:13:44
	System	27 Apr 2021 14:13:44

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '18 Oct 2022 00:01'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:57:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered '22 Oct 2022 23:59'	System	19 Nov 2020 08:45:31

US3592196

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:57:06

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)	25 Apr 2021 20:26:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-27T15:34:33-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd59795c7-5ceb-4d1a-af0c-6cb809c1a8d5'	System	27 Feb 2021 21:34:42
User entered 'No (N)'	System	27 Feb 2021 21:34:42

US3592196

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:57:06

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:26:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DADB1EC3-3FB3-44B3-92F6-E1521AA2A9D7)', Time: '2021-02-27T15:34:38-06:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: 'd59795c7-5ceb-4d1a-af0c-6cb809c1a8d5' User entered '27 Feb 2021 21:34:38'	System	27 Feb 2021 21:34:42
	System	27 Feb 2021 21:34:42

US3592196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:53:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:14:43

US3592196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:53:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:25
User entered '5 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 23:14:43

US3592196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:53:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Nov 2020 23:14:43

US3592196

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:53:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:25
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 23:14:43

US3592196

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User signature succeeded.	Terry Poling (b) (4)	05 Mar 2021 16:53:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 23:14:52

US3592196

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:46:01
User entered 'l'	System	17 Nov 2020 23:14:52

US3592196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 17:52:53

US3592196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:51
User entered '12 Dec 2020'	(b) (4), (b) (6)	14 Dec 2020 17:52:53

US3592196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Dec 2020 17:52:53

US3592196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:18:51
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 17:52:53

US3592196

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:20:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 17:52:58

US3592196

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User entered 'l'	System	14 Dec 2020 17:52:58

US3592196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 18:21:44

US3592196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:13
User entered '11 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 18:21:44

US3592196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 18:21:44

US3592196

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:13
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 18:21:44

US3592196

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 18:21:33

US3592196

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User entered 'l'	System	20 Jan 2021 18:21:33

US3592196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 21:35:08

US3592196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:03
User entered '10 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 21:35:08

US3592196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 21:35:08

US3592196

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:03
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 21:35:08

US3592196

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:10:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 21:35:23

US3592196

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:03:56
User entered 'l'	System	12 Feb 2021 21:35:23

US3592196

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:54:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:29:33

US3592196

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:54:17
User entered '2 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 20:29:33

US3592196

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[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 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:54:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Mar 2021 20:29:33

US3592196

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User entered 'VISIT4'	System	05 Mar 2021 20:29:33

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User closed query 'Please enter vitals completed on 02-Mar-2021' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:20:28
Query 'Please enter vitals completed on 02-Mar-2021' answered with 'vitals entered' (Site from CRA).	Diandra Henriques (b) (4)	14 Apr 2021 20:57:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User opened query 'Please enter vitals completed on 02-Mar-2021' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:02:34
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 17:44:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered '02 Mar 2021' reason for change: Data Entry Error	Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User entered empty.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:44:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered '15:15' reason for change: Data Entry Error	Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User entered empty.	(b) (4)	(b) (4), (b) (6)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:44:50 06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User entered '02 Mar 2021 15:15'	System	14 Apr 2021 20:57:23
User entered empty.	System	06 Apr 2021 17:44:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered '36.7' C reason for change: Data Entry Error	Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User entered empty.	(b) (4)	(b) (4), (b) (6)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:44:50 06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User entered empty.	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:44:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 17:44:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered '90' reason for change: Data Entry Error	Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User entered empty.	(b) (4)	(b) (4), (b) (6)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:44:50 06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User entered 'bpm'	System	14 Apr 2021 20:57:23
User entered empty.	System	06 Apr 2021 17:44:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered '16' reason for change: Data Entry Error	Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User entered empty.	(b) (4)	(b) (4), (b) (6)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:44:50 06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User entered 'breaths/min'	System	14 Apr 2021 20:57:23
User entered empty.	System	06 Apr 2021 17:44:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered '94' reason for change: Data Entry Error	Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User entered empty.	(b) (4)	(b) (4), (b) (6)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:44:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User entered 'mmHg'	System	14 Apr 2021 20:57:23
User entered empty.	System	06 Apr 2021 17:44:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 16:20:30
User entered '62' reason for change: Data Entry Error	Diandra Henriques (b) (4)	14 Apr 2021 20:57:23
User entered empty.	(b) (4)	(b) (4), (b) (6)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:44:50
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User entered 'mmHg'	System	14 Apr 2021 20:57:23
User entered empty.	System	06 Apr 2021 17:44:50
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	06 Apr 2021 17:37:34
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	01 Apr 2021 19:54:48

US3592196

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:55:17
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 20:30:08

US3592196

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:55:17
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 20:30:08

US3592196

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:55:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:29:57

US3592196

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:55:24
User entered '2 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 20:29:57

US3592196

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:55:24
User entered '15:31'	(b) (4), (b) (6)	05 Mar 2021 20:29:57

US3592196

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User entered '2 Mar 2021 15:31'	System	05 Mar 2021 20:29:57

US3592196

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:55:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:30:01

US3592196

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:21:07
User entered 'l'	System	05 Mar 2021 20:30:01

US3592196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	03 May 2021 19:54:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:14:24

US3592196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	03 May 2021 19:54:32
User entered '12 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:14:24

US3592196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	03 May 2021 19:54:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:14:24

US3592196

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	03 May 2021 19:54:32
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:14:24

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	03 May 2021 19:54:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 17:15:11

US3592196

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 17:15:11

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Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:06

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:00:31
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:56:58
Query 'Please clarify as subject was positive on lab report and no action taken! ' canceled (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 19:56:56
User opened query 'Please clarify as subject was positive on lab report and no action taken! ' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:07:48
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 20:06:43
User closed query 'According to lab results subject was COVID 19 positive, reported on 13 Sep 2020. There are not visit data entered. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 16:33:13
Query 'According to lab results subject was COVID 19 positive, reported on 13 Sep 2020. There are not visit data entered. Please confirm and update.' answered with 'subject was asymptomatic, no illness visit performed' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	21 Jan 2021 17:42:01
User opened query 'According to lab results subject was COVID 19 positive, reported on 13 Sep 2020. There are not visit data entered. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 17:27:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Jan 2021 17:26:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 17:22:16
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 17:22:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Nov 2020 08:58:58
Query 'Data is required. Please complete.' answered with 'page populated in error ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 20:38:16
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 20:38:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:38:07
User entered '21 Aug 2020'	(b) (4), (b) (6)	02 Oct 2020 20:28:10

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:06

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:00:31
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint activated with code reason code Data required.	(b) (4)	12 Jan 2021 17:26:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 17:22:16
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 17:22:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Nov 2020 08:59:00
Query 'Data is required. Please complete.' answered with 'page populated in error ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 20:38:00
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:28:10
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:28:10

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Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:06

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:00:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Jan 2021 17:26:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 17:22:16
User entered empty.	System	02 Oct 2020 20:28:10

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:06

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:00:31
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint activated with code reason code Data required.	(b) (4)	12 Jan 2021 17:26:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 17:22:16
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 17:22:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Nov 2020 08:59:02
Query 'Data is required. Please complete.' answered with 'page populated in error ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 20:38:02
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:47:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:47:04
User entered 'Safety Call (Safety Call)'	(b) (4), (b) (6)	02 Oct 2020 20:28:10

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:57:06

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:00:31
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:26:06
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Jan 2021 17:22:16
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 17:22:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Nov 2020 08:59:04
Query 'Data is required. Please complete.' answered with 'page populated in error ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 20:38:05
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:47:04
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:47:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:28:10

US3592196

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

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:05:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:04:25

US3592196

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

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:05:27
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:04:25

US3592196

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

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[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 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:05:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Feb 2021 20:04:25

US3592196

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

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 20:04:25

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:06
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:04:57

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[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 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:14:45

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:04:57

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:14:45

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:06
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:04:57

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:06
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Feb 2021 20:04:57

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:06
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Feb 2021 20:04:57

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:06
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	08 Feb 2021 20:04:57

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:04:57

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'I'	System	08 Feb 2021 20:04:57

US3592196

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

Form: Unblinding

Generated On: 11 Aug 2021 22:57:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'I'	System	08 Feb 2021 20:04:57

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '68.1' kg	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered empty.	System	08 Feb 2021 20:06:53
DataPoint set to visible.	System	08 Feb 2021 20:04:57

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '68.1' kg	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered empty.	System	08 Feb 2021 20:06:53
DataPoint set to visible.	System	08 Feb 2021 20:04:57

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User accepted default value 'Pre-Dose (PREDOSE)'		08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '09:30'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered '4 Feb 2021 09:30'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '36.9' C	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '71'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'bpm'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '16'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'breaths/min'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '96'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'mmHg'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '63'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'mmHg'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered missing code ND - Not Done.	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '68.1' kg	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:57:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered empty.	System	08 Feb 2021 20:06:53
DataPoint set to visible.	System	08 Feb 2021 20:04:57

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User accepted default value 'Post-Dose (POSTDOSE)'		08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '10:33'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered '4 Feb 2021 10:33'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '97.5' F	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '70'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'bpm'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '16'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'breaths/min'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '105'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'mmHg'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:28
User entered '62'	(b) (4), (b) (6)	08 Feb 2021 20:06:53

US3592196

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'mmHg'	System	08 Feb 2021 20:06:53

US3592196

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:07:07

US3592196

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:03:59
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:07:07

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:07:29

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:09
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:07:29

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

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 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:09
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 20:07:29

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'mRNA-1273'	System	08 Feb 2021 20:07:29
DataPoint set to visible.	System	08 Feb 2021 20:04:57

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:09
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:07:29

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:09
User entered '10:01'	(b) (4), (b) (6)	08 Feb 2021 20:07:29

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered '4 Feb 2021 10:01'	System	08 Feb 2021 20:07:29

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:09
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Feb 2021 20:07:29

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:04:09
User entered 'ONCE'	System	08 Feb 2021 20:07:29

US3592196

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

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 20:07:29

US3592196

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:07:47

US3592196

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:16
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:07:47

US3592196

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:16
User entered '09:45'	(b) (4), (b) (6)	08 Feb 2021 20:07:47

US3592196

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered '4 Feb 2021 09:45'	System	08 Feb 2021 20:07:47

US3592196

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:07:57

US3592196

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:24
User entered '4 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 20:07:57

US3592196

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:24
User entered '09:47'	(b) (4), (b) (6)	08 Feb 2021 20:07:57

US3592196

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:57:06

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered '4 Feb 2021 09:47'	System	08 Feb 2021 20:07:57

US3592196

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

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 20:08:02

US3592196

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

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'I'	System	08 Feb 2021 20:08:02

US3592196

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 21:34:51

US3592196

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:34
User entered '11 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 21:34:51

US3592196

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 21:34:51

US3592196

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:34
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 21:34:51

US3592196

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:04:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 21:34:55

US3592196

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'l'	System	12 Feb 2021 21:34:55

US3592196

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'I'	System	12 Feb 2021 21:34:55
DataPoint set to visible.	System	12 Feb 2021 21:34:55

US3592196

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:04:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:31:19

US3592196

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:04:21
User entered '2 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 20:31:19

US3592196

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:04:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Mar 2021 20:31:19

US3592196

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'OLD29'	System	05 Mar 2021 20:31:19

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '2 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '15:15'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered '2 Mar 2021 15:15'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '36.7' C	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '90'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'bpm'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '16'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'breaths/min'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '94'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'mmHg'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '62'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'mmHg'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 13 Apr 2021 19:05:39
User entered '2 Mar 2021'		05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '16:30'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered '2 Mar 2021 16:30'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '98.0' F	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '87'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'bpm'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '16'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'breaths/min'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '125'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'mmHg'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:05:39
User entered '66'	(b) (4), (b) (6)	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'mmHg'	System	05 Mar 2021 20:32:45

US3592196

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:06:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:33:14

US3592196

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:06:05
User entered '2 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 20:33:14

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:14:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:14:20
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

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)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 19:14:22
User entered empty.		05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'mRNA-1273'	System	05 Mar 2021 20:33:36
DataPoint set to visible.	System	12 Feb 2021 21:34:55

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:14:24
User entered '2 Mar 2021'	(b) (4), (b) (6)	05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:14:36
User entered '15:58'	(b) (4), (b) (6)	05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered '2 Mar 2021 15:58'	System	05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:09:44
User closed query 'Source documents treatment was administered in the right arm. please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:09:43
Query 'Source documents treatment was administered in the right arm. please review and update accordingly. ' answered with 'Reviewed pharmacy records, Left arm was used, source corrected.' (Site from CRA).	Diandra Henriques (b) (4) (b) (4)	14 Apr 2021 21:00:33
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	14 Apr 2021 20:58:36
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	14 Apr 2021 20:58:36
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	14 Apr 2021 20:58:36
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	14 Apr 2021 20:12:44
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Diandra Henriques (b) (4) (b) (4)	14 Apr 2021 20:12:44
User opened query 'Source documents treatment was administered in the right arm. please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:15:32
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:14:38
User entered 'ONCE'	System	05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:57:06

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 20:33:36

US3592196

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:15:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 20:33:18

US3592196

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:54:01
User entered 'l'	System	05 Mar 2021 20:33:18

US3592196

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4)	13 Apr 2021 19:21:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 14:31:27

US3592196

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4)	13 Apr 2021 19:21:30
User entered '9 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 14:31:27

US3592196

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4)	13 Apr 2021 19:21:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Mar 2021 14:31:27

US3592196

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:57:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4)	13 Apr 2021 19:21:30
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:31:27

US3592196

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:33:38
DataPoint Verified.	(b) (4)	13 Apr 2021 19:21:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 14:31:46

US3592196

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:57:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:11:49
User entered 'l'	System	30 Mar 2021 14:31:46

US3592196

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:19:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 14:32:05

US3592196

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:19:58
User entered '29 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 14:32:05

US3592196

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:19:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Mar 2021 14:32:05

US3592196

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:57:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 14:32:05

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered '29 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered '13:14'	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:14'	System	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered '36.8' C	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered '75'	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered '16'	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered '120'	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:20
User entered '75'	(b) (4), (b) (6)	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:57:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 14:33:09

US3592196

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:38
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 14:32:17

US3592196

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:57:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:38
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:32:17

US3592196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 14:32:27

US3592196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:51
User entered '29 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 14:32:27

US3592196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4)	13 Apr 2021 19:20:51
User entered '13:20'	(b) (4), (b) (6)	30 Mar 2021 14:32:27

US3592196

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:57:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:20'	System	30 Mar 2021 14:32:27

US3592196

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:57:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:42:20
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 21:05:17

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:06:01
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 20:06:01
Data point term sent to Coder	System	24 Nov 2020 19:44:35
User entered 'asymptomatic COVID-19 positive'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered '16 Aug 2020'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User closed query 'Per CDM: Previously Point Noted, Please Provide estimation Time' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 11:07:26
Query 'Per CDM: Previously Point Noted, Please Provide estimation Time' answered with 'done' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:08:57
User entered '10:35' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:08:49
User opened query 'Per CDM: Previously Point Noted, Please Provide estimation Time' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:10:13
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	26 Nov 2020 09:07:34
Query 'Data is required. Please provide.' answered with 'time is unknown ' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 19:46:17
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 19:45:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 19:45:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:45:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 19:44:50
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 19:44:50
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	24 Nov 2020 19:44:50
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 19:44:34
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 10:35'	System	08 Jan 2021 21:08:49
User entered empty.	System	24 Nov 2020 19:45:14
User entered '16 Aug 2020 UN:UN' (non-conformant).	System	24 Nov 2020 19:44:50
User entered empty.	System	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 11:07:31
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:09:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:09:26
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 07:38:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Jan 2021 21:09:45
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Jan 2021 21:09:45
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Jan 2021 21:09:26
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:09:26
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Jan 2021 21:13:11
User entered '23:59' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:13:11
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Jan 2021 21:09:26
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 23:59'	System	08 Jan 2021 21:13:11
User entered empty.	System	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
Query 'Per CDM: Per CCG pg 46, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 10:02:44
User opened query 'Per CDM: Per CCG pg 46, Not Applicable should be used only if Adverse event is prior to first Dose of the investigational product. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:07:49
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 17:27:46
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 19:45:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 19:45:14
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:45:14
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 19:44:34
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 19:45:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 19:45:14
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:45:14
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 19:44:34
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Jan 2021 11:07:40
User closed query 'Per CDM: Per CCGs, As this AE was the primary reason for Dosing discontinuation, Please consider to update Action taken with Investigational product as "Investigational product withdrawn". Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 11:07:37
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Confirm discontinued due to adverse event of COVID which is a selection.' (Site from System).	(b) (4), (b) (6)	08 Jan 2021 21:14:12
Query 'Per CDM: Per CCGs, As this AE was the primary reason for Dosing discontinuation, Please consider to update Action taken with Investigational product as "Investigational product withdrawn". Thank you.' answered with 'done' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:10:48
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	08 Jan 2021 21:10:32
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:10:32
User opened query 'Per CDM: Per CCGs, As this AE was the primary reason for Dosing discontinuation, Please consider to update Action taken with Investigational product as "Investigational product withdrawn". Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:10:46
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 19:45:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 19:45:14

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:45:14
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 19:44:34
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:09:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:27:46
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:27:46
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:57:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:20
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:37:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Mar 2021 14:37:08
Data point term sent to Coder	System	30 Mar 2021 14:35:45
User entered 'acid reflux'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:27
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:29
User entered '8 Oct 2020'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:31
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User entered empty.	System	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:37
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:39
User entered '3 Nov 2020'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:41
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User entered empty.	System	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:44
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:46
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:48
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:50
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:52
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:54
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:14:58
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:06
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 20:15:04
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:15:01
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:08
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:10
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:11
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:13
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:15
User entered 'None (NONE)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:17
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:18
User entered 'l'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:20
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:23
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:15:25
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User entered '0'	System	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42
User entered 'l'	System	30 Mar 2021 14:35:00

US3592196

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:57:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:49:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:57:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:43:13

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:04:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:04:29
Data point term sent to Coder	System	19 Aug 2020 15:03:38
User entered 'levothyroxine'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'hypothyroidism'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '125'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'ug (ug)'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:40:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:11:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:02:37
User entered 'un UNK 1970'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:04:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:04:30
Data point term sent to Coder	System	19 Aug 2020 15:03:39
User entered 'ondansetron'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'nausea'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '4'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:40:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:11:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:03:30
User entered 'un UNK 1993'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:05:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:05:20
Data point term sent to Coder	System	19 Aug 2020 15:04:42
User entered 'estradiol'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'post menopausal'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0.5'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'every other day (QOD)'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:40:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:11:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:04:15
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: MEDROXYPROGESTERONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 03:13:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 03:13:39
Data point term sent to Coder	System	19 Aug 2020 15:05:44
User entered 'medroxyprogesterone'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'post menopausal'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '2.5'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'every other day (QOD)'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:40:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:12:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:05:17
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: SOLIFENACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:34:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:34:17
Data point term sent to Coder	System	19 Aug 2020 15:06:47
User entered 'solifenacin'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'nocturia'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '5'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:40:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:12:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:06:06
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:09:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:09:19
Data point term sent to Coder	System	19 Aug 2020 15:07:49
User entered 'potassium chloride ER'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'hypokalemia'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '10'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'meQ'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:41:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:12:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:07:04
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 11:41:13
User entered '0'	(D) (4), (D) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:09:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:09:22
Data point term sent to Coder	System	19 Aug 2020 15:08:52
User entered 'glucosamine chondroitin'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'osteoarthritis'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 11:10:03
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'MH date corrected' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:15:48
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:54:09
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:41:42
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:12:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:08:23
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:10:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:10:30
Data point term sent to Coder	System	19 Aug 2020 15:09:55
User entered 'vitamin c'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 15:10:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 15:10:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 15:10:11
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 15:09:42
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '500'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:41:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:10:08
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:09:42
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CITRATE;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM CITRATE WITH VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:13:38
Data point term sent to Coder	System	19 Aug 2020 15:12:01
User entered 'CALCIUM WITH VITAMIN D3'	(b) (4), (b) (6)	19 Aug 2020 15:11:29
reason for change: Data Entry Error		
User entered 'calcium with vitamin D'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:42:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:11:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:11:10
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:15:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:15:34
Data point term sent to Coder	System	19 Aug 2020 15:14:06
User entered 'Vitamin D3'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '1000'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'IU (IU)'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:42:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:13:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:13:18
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
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) (b) (4)	19 Aug 2020 15:16:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:16:39
Data point term sent to Coder	System	19 Aug 2020 15:15:08
User entered 'Multivitamin'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:43:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:14:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:14:08
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:16:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:16:38
Data point term sent to Coder	System	19 Aug 2020 15:15:09
User entered 'docusate sodium'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:41:55
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'medical history has been updated' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 20:05:28
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:52:38
User entered 'constipation'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '100'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'three times daily (TID)'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:43:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:14:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:14:55
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:16:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:16:40
Data point term sent to Coder	System	19 Aug 2020 15:16:15
User entered 'melatonin'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'nutritional supplement'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '10'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:43:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:15:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:15:46
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 11:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 11:51:44
Data point term sent to Coder	System	19 Aug 2020 15:17:16
User entered 'methocarbamol'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'fibromyalgia'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '500'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'three times daily (TID)'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:47:14
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct as entered' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 15:16:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:16:35
User entered 'un Jan 2020'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:43:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:43:52
Data point term sent to Coder	System	19 Aug 2020 15:18:19
User entered 'naproxen sodium'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'osteoarthritis'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '440'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 11:10:18
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'Confirm started after MH start date' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:16:47
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:54:37
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:53:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:17:27
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:17:27

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTSYNONYM: SIMETHICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:20:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:20:20
Data point term sent to Coder	System	19 Aug 2020 15:19:22
User entered 'simethicone'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 11:10:22
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH term updated' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:17:42
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:53:06
User entered 'excess stomach gas'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '80'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:53:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:19:11
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:19:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:21:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:21:51
Data point term sent to Coder	System	19 Aug 2020 15:20:23
User entered 'diphenhydramine'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'seasonal allergies'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '25'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:53:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:20:20
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:20:20

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:22:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:22:23
Data point term sent to Coder	System	19 Aug 2020 15:21:24
User entered 'pseudoephedrine'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'seasonal allergies'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '120'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:53:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 15:21:09
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 15:21:09

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:03:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:03:50
Data point term sent to Coder	System	08 Sep 2020 22:02:48
User entered 'naproxen'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'headache'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '440'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '22 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '22 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:11:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Does not meet AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 00:25:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:43:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User entered empty.	System	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User entered empty.	System	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:04
User entered empty.	System	08 Sep 2020 22:02:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:05:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:05:52
Data point term sent to Coder	System	08 Sep 2020 22:04:51
User entered 'naproxen'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'muscle aches'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '440'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '20 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '20 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:11:35
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria. ' answered with 'Does not meet AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 00:25:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 05:44:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User entered empty.	System	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User entered empty.	System	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:06
User entered empty.	System	08 Sep 2020 22:04:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
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) (b) (4)	17 Nov 2020 23:19:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 23:19:51
Data point term sent to Coder	System	17 Nov 2020 23:19:26
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:08:44
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' (Site from DM). Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' answered with 'corrected to yes ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:51:46
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 20:03:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:03:06
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis, refer to CCGs. Update as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 12:49:10
User entered 'No (N)'	(b) (4), (b) (6)	12 Jan 2021 17:28:48
	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'l'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'injection'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'once (ONCE)'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered '16 Sep 2020'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User entered empty.	System	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User entered empty.	System	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:49:10
User entered empty.	System	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:09:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:09:46
Data point term sent to Coder	System	14 Dec 2020 18:09:22
User entered 'restasis'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'dry eye'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'I'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'gtt'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'ophthalmic'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'un UNK 2010'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 18:08:43

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: AMINO ACIDS AND DERIVATIVES, PRODUCT: LYSINE, PRODUCTSYNONYM: L LYSINE [LYSINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:12:50
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 Dec 2020 01:12:50
Data point term sent to Coder	System	14 Dec 2020 18:09:22
User entered 'L-lysine'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'cold sores prophylaxis'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '500'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'twice daily (BID)'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:28:48
User entered 'un UNK 2010'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:48
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 18:09:22

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 21:37:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:37:13
Data point term sent to Coder	System	12 Apr 2021 21:21:00
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 21:20:07
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:09:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:50:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:50:54
Data point term sent to Coder	System	12 Feb 2021 21:37:19
User entered 'famotidine'	(b) (4), (b) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:09:45
User entered 'No (N)'	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 19:08:13
User closed query 'According to subject source and concomitant medications log the indication for this medication is 'Acid Reflux', but eDC reports indication as 'Acid Redlux'. Please consider correcting spelling. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:08:11
Query 'According to subject source and concomitant medications log the indication for this medication is 'Acid Reflux', but eDC reports indication as 'Acid Redlux'. Please consider correcting spelling. Thank you. ' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 21:20:23
User entered 'ACID Reflux' reason for change: New Information	(b) (4), (b) (6)	12 Apr 2021 21:20:07
User opened query 'According to subject source and concomitant medications log the indication for this medication is 'Acid Reflux', but eDC reports indication as 'Acid Redlux'. Please consider correcting spelling. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 20:10:42
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:35:49
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'AE added ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:36:23
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 01:41:37
User entered 'acid redlux'	(b) (4), (b) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:17
User entered '40'	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:18
User entered 'mg (mg)'	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:21
User entered empty.	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:27
User entered 'once daily (QD)'	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:30
User entered empty.	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:32
User entered 'Oral (ORAL)'	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:35
User entered empty.	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:40
User entered '08 Oct 2020'	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:12:42
User entered '0'	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 06:28:12
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'ongoing at last contact ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 21:36:28
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 04:33:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:13:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:02
User entered empty.	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:04
User entered 'No (N)'	(D) (4), (D) (6)	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Feb 2021 21:37:11

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
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: GLUCOCORTICIDS, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 14:33:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 14:33:53
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 20:13:20
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening OSTEOARTHRITIS during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:35:59
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening OSTEOARTHRITIS during this timeframe; update Con Med indication or provide clarification. ' answered with 'Not a worsening of' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:37:24
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening OSTEOARTHRITIS during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 01:41:50

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Name of Medication](#)

Audit	User	Time (GMT)
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: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:38:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:38:02
Data point term sent to Coder	System	12 Feb 2021 21:46:59
User entered 'cortisone'	(b) (4), (b) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:27
User entered 'No (N)'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:31
User entered 'osteoarthritis'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:34
User entered '50'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:36
User entered 'mg (mg)'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:38
User entered empty.	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:42
User entered 'other (OTHER)'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:44
User entered '3 months'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:46
User entered 'Other (OTHER)'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:48
User entered 'intra-articular injection'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:50
User entered '28 Jan 2021'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:52
User entered '0'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:54
User entered 'Yes (Y)'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:56
User entered empty.	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	01 Apr 2021 20:13:58
User entered 'No (N)'	(D) (4), (D) (6)	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 11 Aug 2021 22:57:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 21:46:42

US3592196

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:57:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Terry Poling (b) (4)	16 Apr 2021 15:53:59
DataPoint Verified.	(b) (4) (D) (4), (D) (6)	12 Jan 2021 17:28:55
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 21:05:32

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered 'Visit 2 Day 29 (VISIT2)'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User closed query 'There are no selections for Case Report Form. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:26:10
Query 'There are no selections for Case Report Form. Please review and reconcile.' answered by data change (Site from System).	System	02 Oct 2020 19:26:10
User opened query 'There are no selections for Case Report Form. Please review and reconcile.' (Site from System).	System	02 Oct 2020 19:05:22
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:26:10
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:26:10
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:26:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 19:26:44
User entered '13 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 19:26:44
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:05:22
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered 'l'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User closed query 'There are no selections for Description of Relationship to COVID-19. Please select at least one relationship.' (Site from System).	System	24 Nov 2020 20:33:36
Query 'There are no selections for Description of Relationship to COVID-19. Please select at least one relationship.' answered by data change (Site from System).	System	24 Nov 2020 20:33:36
User opened query 'There are no selections for Description of Relationship to COVID-19. Please select at least one relationship.' (Site from System).	System	02 Oct 2020 19:05:22
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '1' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 20:33:36
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:57:06

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:16:44
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:29:47
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:57:06

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:02:42
User entered '16 Aug 2020'	(b) (4), (b) (6)	24 Nov 2020 19:42:08

US3592196

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:57:06

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:32:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:02:42
Query 'Per CDM: Per CCGs, Please consider to update this field to AE (specify) or SAE (specify) accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:27:42
User opened query 'Per CDM: Per CCGs, Please consider to update this field to AE (specify) or SAE (specify) accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:14:44
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	24 Nov 2020 19:42:08

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:57:06

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 06:32:56
User signature succeeded.	Terry Poling (b) (4)	28 Apr 2021 08:32:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:02:42
Query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:27:44
User opened query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:15:30
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:42:08