

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

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:38:50

All time stamps listed in this document are displayed in GMT

US3592196

Form: Participant Creation

Generated On: 26 Nov 2020 09:38:50

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

Generated On: 26 Nov 2020 09:38:50

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 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:38:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:38:50

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1969
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	DRY EYE
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1969
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	HYPOKALEMIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	NAUSEA
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	OCCASIONAL EXCESS GAS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	NOCTURIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	OSTEOARTHRITIS GENERAL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

Condition	FIBROMYALGIA
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	HEADACHES OCCASIONALLY
Start date (dd MMM yyyy)	UN UNK 1957
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 09:38:50

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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

Generated On: 26 Nov 2020 09:38:50

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	16 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:20 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 10:20
Height (<i>xxx.x</i>)	155.0 cm
Weight (<i>xxx.x</i>)	67.3 kg
BMI (<i>xxx.x</i>)	28.01249 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Date of assessment (<i>dd MMM yyyy</i>)	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 (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2000
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 09:38:50

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 AUG 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:38:50

Collection date (<i>dd MMM yyyy</i>)			16 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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 ☒

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

Yes ☐	
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: 26 Nov 2020 09:38:50

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 ☒

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:50

Yes ☐	
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: 26 Nov 2020 09:38:50

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 ☒

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

Yes ☐	
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: 26 Nov 2020 09:38:50

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 ☒

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:50

Yes ☐	
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: 26 Nov 2020 09:38:50

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 ☒

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

Yes ☐	
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: 26 Nov 2020 09:38:50

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 ☒

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:50

Yes ☐	
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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 09:38:50

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3592196

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:37 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:37
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3592196

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:53 (24 HR)
Collection date and time (derived)	13 OCT 2020 11:53

US3592196

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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 ☒ 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 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 61
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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

17 OCT 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 68
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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

24 OCT 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

31 OCT 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

07 NOV 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ 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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

14 NOV 2020 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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 ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

26 FEB 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

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

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23 APR 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2022 00:01

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23 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

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30 JUL 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:38:50

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:38:50

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

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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

[Patient Cloud Close Date & Time](#)

15 OCT 2022 23:59

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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 ☐ 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: 26 Nov 2020 09:38:50

Please contact your study clinic immediately. Click below to confirm that you have read this 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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592196

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

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 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:50

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:38:50

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3592196

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:38:50

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)

Generated On: 26 Nov 2020 09:38:50

AEID	
Adverse event	ASYMPTOMATIC COVID-19 POSITIVE
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)	16 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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	
v6.020 DTW (1102)	318 of 1845

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☐ Not Applicable ☒
Relationship to Study Procedure	Not Related ☐ Related ☐ Not Applicable ☒
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:38:50

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

Yes ☒

No ☐

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

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK	1970
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1993
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes ☒	No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:38:50

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK	1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☐

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:38:50

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

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:38:50

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 ☐ Intramuscular ☒

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:38:50

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3592196

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:38:50

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:38:50

Visit	Screening	☐
	Visit 1 Day 1	☐
	Visit 2 Day 29	☒
	Visit 3 Day 57	☐
	Visit 4 Day 209	☐
	Visit 5 Day 394	☐
	Visit 6 Day 759	☐

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
End of Study / Study Discontinuation	False

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:38:50

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

Generated On: 26 Nov 2020 09:38:50

Date of dosing discontinuation (dd MMM yyyy)

16 AUG 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

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

US3592196

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3592196'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Aug 2020 14:59:10

US3592196

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:40:07

US3592196

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 14:59:11

US3592196

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Aug 2020 16:40:07

US3592196

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	16 Aug 2020 16:40:07

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 14:59:12

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Age](#)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '69'	System	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Ethnicity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:50

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 16:40:19

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 16:40:29

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 14:59:11

US3592196

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 16:40:36

US3592196

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:40:36

US3592196

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:38:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:39:36

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 1969'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 1969'	System	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '1969'	System	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:39:54

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '2010'	System	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:40:06

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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: Coder Import	(b) (4)	19 Aug 2020 14:41:30
Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eye - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import	19 Aug 2020 14:41:30
Data point term sent to Coder	(b) (4)	
User entered 'dry eye'	System	19 Aug 2020 14:40:44
	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '2010'	System	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:40:36

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '1990'	System	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:40:53

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:44:54

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:45:18

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '1991'	System	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:45:27

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '2010'	System	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:45:47

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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)	19 Aug 2020 14:48:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '2000'	System	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:45:59

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '2000'	System	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:46:09

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '2005'	System	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:46:24

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 1993'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '1993'	System	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:46:39

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
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) (b) (4)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 1957'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 1957'	System	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '1957'	System	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:46:55

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (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)	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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '2000'	System	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 20:04:07

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '10:20'	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 10:20'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 14:48:33

US3592196

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:50

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:50

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:38:50

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:49:47

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

[Other](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Specify](#)

Audit	User	Time (GMT)
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

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:50

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 14:50:38

US3592196

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	19 Aug 2020 14:51:10

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:50

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

What was the participant's randomization number?

Audit	User	Time (GMT)
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) [REDACTED]	16 Aug 2020 16:09:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:50

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:50

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:50

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:50

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:50

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 14:52:14

US3592196

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:50

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Height

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Weight

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Height

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Weight

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 09:38:50

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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 (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered '10:32'	(b) (4), (b) (6)	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:50

Height

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Weight

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Pulse (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 14:57:01

US3592196

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:35'	(b) (4), (b) (6)	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:35'	System	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Aug 2020 16:40:55

US3592196

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 14:55:07

US3592196

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 14:55:22

US3592196

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 14:55:22

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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-ae75-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: 26 Nov 2020 09:38:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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-ae75-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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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-ae75-e8b8e82283bb'	System	16 Aug 2020 17:16:47
User entered 'No (N)'	System	16 Aug 2020 17:16:47

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Aug 2020 17:16:47
User entered '16 Aug 2020 12:16'	System	16 Aug 2020 17:16:47

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:30:45
User entered 'Yes (Y)'	System	17 Aug 2020 23:30:45

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:50

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:30:45
User entered '98.9'	System	17 Aug 2020 23:30:45

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:30:45
User entered 'No (N)'	System	17 Aug 2020 23:30:45

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:30:45
User entered '17 Aug 2020 18:30'	System	17 Aug 2020 23:30:45

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:35:22
User entered 'Yes (Y)'	System	18 Aug 2020 23:35:22

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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-2ecea776f9e0'	System	18 Aug 2020 23:35:22
User entered '98.8'	System	18 Aug 2020 23:35:22

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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-2ecea776f9e0'	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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-2ecea776f9e0'	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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:05:24
User entered 'Yes (Y)'	System	20 Aug 2020 01:05:24

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:05:24
User entered '98.2'	System	20 Aug 2020 01:05:24

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:05:24
User entered 'No (N)'	System	20 Aug 2020 01:05:24

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:05:24
User entered '19 Aug 2020 20:05'	System	20 Aug 2020 01:05:24

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Aug 2020 22:30:04
User entered 'Yes (Y)'	System	20 Aug 2020 22:30:04

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 22:30:04
User entered 'Yes (Y)'	System	20 Aug 2020 22:30:04

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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). 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 '1'	System	20 Aug 2020 22:30:04
	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: 26 Nov 2020 09:38:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:04:36
User entered 'Yes (Y)'	System	21 Aug 2020 23:04:36

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:04:36
User entered '98.4'	System	21 Aug 2020 23:04:36

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:04:36
User entered '21 Aug 2020 18:04'	System	21 Aug 2020 23:04:36

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	23 Aug 2020 01:57:25
User entered '97.9'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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). 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: 26 Nov 2020 09:38:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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 '0'	System	23 Aug 2020 01:57:25

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	23 Aug 2020 23:08:26
User entered 'Yes (Y)'	System	23 Aug 2020 23:08:26

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:38:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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-e364-4a36-afc0-5e617b68a256'	System	23 Aug 2020 23:08:26
User entered '97.7'	System	23 Aug 2020 23:08:26

US3592196

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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-e364-4a36-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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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'	System	16 Aug 2020 17:17:29
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	16 Aug 2020 17:17:29
User entered 'No (N)'	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	16 Aug 2020 17:17:29
User entered 'No (N)'	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Aug 2020 17:17:29
User entered '16 Aug 2020 12:17'	System	16 Aug 2020 17:17:29

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:17:17
User entered 'None (1)'	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:17:17
User entered 'No (N)'	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:17:17
User entered 'No (N)'	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:17:17
User entered '17 Aug 2020 18:17'	System	17 Aug 2020 23:17:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:30:21
User entered '18 Aug 2020 18:30'	System	18 Aug 2020 23:30:21

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:02:17
User entered 'None (1)'	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:02:17
User entered 'No (N)'	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:02:17
User entered 'No (N)'	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:02:17
User entered 'None (1)'	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:02:17
User entered '19 Aug 2020 20:02'	System	20 Aug 2020 01:02:17

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 22:07:13
User entered 'No (N)'	System	20 Aug 2020 22:07:13

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 22:07:13
User entered 'No (N)'	System	20 Aug 2020 22:07:13

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 22:07:13
User entered '20 Aug 2020 17:07'	System	20 Aug 2020 22:07:13

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:04:53
User entered 'None (1)'	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:04:53
User entered 'No (N)'	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:04:53
User entered 'No (N)'	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:04:53
User entered 'None (1)'	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:04:53
User entered '21 Aug 2020 18:04'	System	21 Aug 2020 23:04:53

US3592196

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	16 Aug 2020 17:18:27
User entered 'No (N)'	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	16 Aug 2020 17:18:27
User entered '16 Aug 2020 12:18'	System	16 Aug 2020 17:18:27

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

HEADACHE

Audit	User	Time (GMT)
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'	System	17 Aug 2020 13:26:26
User entered 'None (0)'	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:50

FATIGUE

Audit	User	Time (GMT)
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'	System	17 Aug 2020 13:26:26
User entered 'None (0)'	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	17 Aug 2020 13:26:26
User entered 'None (0)'	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	17 Aug 2020 13:26:26
User entered 'None (0)'	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:50

CHILLS

Audit	User	Time (GMT)
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'	System	17 Aug 2020 13:26:26
User entered 'None (0)'	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	17 Aug 2020 13:26:26
User entered 'No (N)'	System	17 Aug 2020 13:26:26

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

HEADACHE

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:18:20
User entered 'None (0)'	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

FATIGUE

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:18:20
User entered 'None (0)'	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:18:20
User entered 'None (0)'	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:18:20
User entered 'None (0)'	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:18:20
User entered 'None (0)'	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

CHILLS

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:18:20
User entered 'None (0)'	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:18:20
User entered 'No (N)'	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	17 Aug 2020 23:18:20
User entered '17 Aug 2020 18:18'	System	17 Aug 2020 23:18:20

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

HEADACHE

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:31:12
User entered 'None (0)'	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:50

FATIGUE

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:31:12
User entered 'None (0)'	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:31:12
User entered 'None (0)'	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:50

CHILLS

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:31:12
User entered 'None (0)'	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	18 Aug 2020 23:31:12
User entered '18 Aug 2020 18:31'	System	18 Aug 2020 23:31:12

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

HEADACHE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:01:19
User entered 'None (0)'	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

FATIGUE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:01:19
User entered 'None (0)'	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:01:19
User entered 'None (0)'	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:01:19
User entered 'None (0)'	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:01:19
User entered 'None (0)'	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

CHILLS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:01:19
User entered 'None (0)'	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:01:19
User entered 'No (N)'	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:01:19
User entered '19 Aug 2020 20:01'	System	20 Aug 2020 01:01:19

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

HEADACHE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:38:50

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:38:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:38:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 22:06:16
User entered '20 Aug 2020 17:06'	System	20 Aug 2020 22:06:16

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:05:29
User entered 'None (0)'	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:05:29
User entered 'None (0)'	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:05:29
User entered 'None (0)'	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:05:29
User entered 'None (0)'	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:05:29
User entered 'None (0)'	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

CHILLS

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:05:29
User entered 'None (0)'	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:05:29
User entered 'No (N)'	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 23:05:29
User entered '21 Aug 2020 18:05'	System	21 Aug 2020 23:05:29

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

FATIGUE

Audit	User	Time (GMT)
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'	System	23 Aug 2020 01:58:08
User entered 'None (0)'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	23 Aug 2020 01:58:08
User entered 'None (0)'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	23 Aug 2020 01:58:08
User entered 'None (0)'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Aug 2020 01:58:08
User entered 'None (0)'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:50

CHILLS

Audit	User	Time (GMT)
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'	System	23 Aug 2020 01:58:08
User entered 'None (0)'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	23 Aug 2020 01:58:08
User entered 'No (N)'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 01:58:08
User entered '22 Aug 2020 20:58'	System	23 Aug 2020 01:58:08

US3592196

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	23 Aug 2020 23:06:04
User entered 'None (0)'	System	23 Aug 2020 23:06:04

US3592196

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:38:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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'	System	23 Aug 2020 23:05:49
User entered 'No (N)'	System	23 Aug 2020 23:05:49

US3592196

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:50

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 23:05:49
User entered '23 Aug 2020 18:05'	System	23 Aug 2020 23:05:49

US3592196

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 21:49:22

US3592196

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:49:30

US3592196

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 21:50:35

US3592196

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:50:47

US3592196

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 21:53:56

US3592196

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 21:54:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	13 Sep 2020 16:40:03

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:50

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:50

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:41:46

US3592196

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:50

Was the physical examination performed?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If No, reason not given](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:42:11

US3592196

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(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: 26 Nov 2020 09:38:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(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: 26 Nov 2020 09:38:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Sep 2020 16:43:20

US3592196

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 16:43:54

US3592196

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:48:09

US3592196

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 18:48:13

US3592196

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:48:13

US3592196

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 18:49:38

US3592196

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 18:49:43

US3592196

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 20:19:38

US3592196

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 20:19:44

US3592196

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	17 Nov 2020 23:10:42

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of measurement](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Nov 2020 23:11:18

US3592196

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 23:12:07

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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: '2020-10-16T17:31:41', 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: 26 Nov 2020 09:38:50

Have you been exposed to someone with 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: '2020-10-16T17:31:49', 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: 26 Nov 2020 09:38:50

[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: '2020-10-16T17:31:57', 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: 26 Nov 2020 09:38:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: '2020-10-24T14:22:59', 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: 26 Nov 2020 09:38:50

Have you been exposed to someone with 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: '2020-10-24T14:23:06', 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: 26 Nov 2020 09:38:50

[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: '2020-10-24T14:23:15', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '9f13a549-5679-459e-9680-15d4bd31a8d6'	System	24 Oct 2020 19:23:18
User entered '24 Oct 2020 14:23:15'	System	24 Oct 2020 19:23:18

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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: '2020-10-31T04:47:19', 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: 26 Nov 2020 09:38:50

Have you been exposed to someone with 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: '2020-10-31T04:47:25', 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: 26 Nov 2020 09:38:50

[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: '2020-10-31T04:47:33', 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: 26 Nov 2020 09:38:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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: '2020-11-13T09:04:49', 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: 26 Nov 2020 09:38:50

Have you been exposed to someone with 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: '2020-11-13T09:04:54', 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: 26 Nov 2020 09:38:50

[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: '2020-11-13T09:05:00', User OID: 'PatientReportedOutcome (US3592196)', ODM File OID: '1fd2f4ab-6337-4dc2-b9c4-ca106280cca0'	System	13 Nov 2020 15:05:05
User entered '13 Nov 2020 09:05:00'	System	13 Nov 2020 15:05:05

US3592196

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

[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 Oct 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: 26 Nov 2020 09:38:50

[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 Oct 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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

[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 Oct 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: 26 Nov 2020 09:38:50

[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 Oct 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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

[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 Oct 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: 26 Nov 2020 09:38:50

[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 Oct 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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

[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 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: 26 Nov 2020 09:38:50

[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 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: 26 Nov 2020 09:38:50

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:45:31
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 08:45:31

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

[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 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: 26 Nov 2020 09:38:50

[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 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: 26 Nov 2020 09:38:50

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

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'	System	19 Nov 2020 15:32:00
User entered 'No (N)'	System	19 Nov 2020 15:32:00

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

Have you been exposed to someone with 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'	System	19 Nov 2020 15:32:00
User entered 'No (N)'	System	19 Nov 2020 15:32:00

US3592196

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 23:14:43

US3592196

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 23:14:52

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:50

[Date of Contact](#)

Audit	User	Time (GMT)
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

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:50

[Time of Contact](#)

Audit	User	Time (GMT)
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

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:50

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:28:10

US3592196

Folder: Covid-19 Assessment 21 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:50

[Type of Contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:38:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Adverse event](#)

Audit	User	Time (GMT)
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) (b) (4)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
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

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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 '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

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:44:34

US3592196

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 19:44:34

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:38:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:11:40
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:02:37

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:11:53
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:03:30

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:11:59
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:04:15

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:12:04
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:05:17

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:12:13
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:06:06

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:12:18
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Reviewed for Data Management.	(b) (4), (b) (6)	20 Aug 2020 11:41:13
User entered '0'	(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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:07:04

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:08:23

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:10:08
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:09:42

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:11:14
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:11:10

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:13:22
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:13:18

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:14:11
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:14:08

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:14:59
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:14:55

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:15:50
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:15:46

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.'	(b) (4), (b) (6)	19 Aug 2020 15:16:39
answered with 'confirm correct as entered' (Site from System).		
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:16:35

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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 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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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)	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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
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
v6.020 DTW (1102)		1753 of 1845

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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 - 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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
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

v6.020 DTW (1102)

1772 of 1845

US3592196

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(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: 26 Nov 2020 09:38:50

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 23:19:00

US3592196

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:38:50

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Visit Date](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Demographics](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Enrollment](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Medical History Summary](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Medical History](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Vital Signs](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Physical Examination](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Childbearing Potential](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Pregnancy Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Randomization](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Exposure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Saliva Collection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Symptom Log](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[COVID-19 Contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Risk of Exposure](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Safety Call](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[All](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Study Treatment not given](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 09:38:50

[Missed Visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Missed Assessment](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Visit performed out of window](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Assessment performed out of window](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Other](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Clinical site closed](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Travel restrictions](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Participant decision](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 19:05:22

US3592196

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:50

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:38:50

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	(b) (4), (b) (6)	24 Nov 2020 19:42:08

US3592196

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:50

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 19:42:08