

US3252127 (Prod: Centex Studies Inc)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:50:23

All time stamps listed in this document are displayed in GMT

US3252127

Form: Participant Creation

Generated On: 26 Nov 2020 10:50:23

[Participant ID](#)

US3252127

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

US3252127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:50:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3252127

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:50:23

Were any significant conditions reported?

Yes ☒

No ☐

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

Condition	GENERAL CEREBRAL ATROPHY
Start date (dd MMM yyyy)	UN JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

Condition	CHRONIC KIDNEY DISEASE STAGE 3
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

Condition	ENDOSCOPY
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:04 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 16:04
Height (<i>xxx.x</i>)	68.7 in
Weight (<i>xxx.x</i>)	199 lb
BMI (<i>xxx.x</i>)	29.70636 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252127

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (*dd MMM yyyy*) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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	

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

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

What was the participant's randomization number? 185790

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 ☐

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:23

Height	ND - Not Done
Weight	ND - Not Done

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 16:04
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	18:24 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 18:24
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3252127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

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.

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (*dd MMM yyyy*) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	11 AUG 2020
What was the treatment time? (00:00-23:59)	17:34 (24 HR)
Treatment Date and Time (derived)	11 AUG 2020 17:34
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 AUG 2020
Collection time (<i>00:00-23:59</i>)	17:16 (24 HR)
Collection date and time (derived)	11 AUG 2020 17:16

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:23

Collection date (<i>dd MMM yyyy</i>)			11 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	17:00	11 AUG 2020 17:00
Nasopharyngeal Swab 2	No		

US3252127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 18:27

PC Open Date & Time

11 AUG 2020 17:54

PC Close Date & Time

11 AUG 2020 20:24

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	12 AUG 2020 11:41
PC Open Date & Time	11 AUG 2020 21:19
PC Close Date & Time	12 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 00:17

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 19:34

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

14 AUG 2020 20:04

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 23:30

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:08

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

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

97.7 °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

17 AUG 2020 19:57

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 18:35

PC Open Date & Time

11 AUG 2020 17:54

PC Close Date & Time

11 AUG 2020 20:24

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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

12 AUG 2020 11:43

PC Open Date & Time

11 AUG 2020 21:19

PC Close Date & Time

12 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

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

13 AUG 2020 00:18

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

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

13 AUG 2020 19:34

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 20:05

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 23:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 22:09

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 19:58

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 18:35
PC Open Date & Time	11 AUG 2020 17:54
PC Close Date & Time	11 AUG 2020 20:24

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 11:44
PC Open Date & Time	11 AUG 2020 21:19
PC Close Date & Time	12 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 19:36
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 20:05
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 23:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 22:09
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 19:59
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

Was Contact Attempted?

Yes ☒

No ☐

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

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

Was Contact Attempted?

Yes ☒

No ☐

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

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

Was Contact Attempted?

Yes ☒

No ☐

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

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	15:39 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 15:39
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	16:41 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 16:41
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3252127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

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.

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (*dd MMM yyyy*) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	8 SEP 2020
What was the treatment time? (00:00-23:59)	16:09 (24 HR)
Treatment Date and Time (derived)	8 SEP 2020 16:09
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	8 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:06 (24 HR)
Collection date and time (derived)	8 SEP 2020 16:06

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:23

Collection date (<i>dd MMM yyyy</i>)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:00	8 SEP 2020 16:00
Nasopharyngeal Swab 2	No		

US3252127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 16:44

PC Open Date & Time

08 SEP 2020 16:29

PC Close Date & Time

08 SEP 2020 18:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °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	09 SEP 2020 00:47
PC Open Date & Time	08 SEP 2020 19:54
PC Close Date & Time	09 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 <input checked="" type="radio"/>
	No <input type="radio"/>

Please record your TEMPERATURE in °F	98.9 °F
---	---------

Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
---	------

To PREVENT pain or fever from occurring	True
--	------

PC Time Stamp	09 SEP 2020 21:58
---------------	-------------------

PC Open Date & Time	09 SEP 2020 12:00
---------------------	-------------------

PC Close Date & Time	10 SEP 2020 11:59
----------------------	-------------------

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	11 SEP 2020 09:45
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 10:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

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

96.4 °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

13 SEP 2020 02:28

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

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**

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

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

97.0 °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

15 SEP 2020 09:55

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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

08 SEP 2020 16:45

PC Open Date & Time

08 SEP 2020 16:29

PC Close Date & Time

08 SEP 2020 18:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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

09 SEP 2020 00:48

PC Open Date & Time

08 SEP 2020 19:54

PC Close Date & Time

09 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 21:58

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

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

11 SEP 2020 09:46

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

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

12 SEP 2020 10:33

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

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

13 SEP 2020 02:28

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

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

15 SEP 2020 09:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 16:45
PC Open Date & Time	08 SEP 2020 16:29
PC Close Date & Time	08 SEP 2020 18:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 00:49
PC Open Date & Time	08 SEP 2020 19:54
PC Close Date & Time	09 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:00
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 09:47
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 10:33
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 02:29
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

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 ☒

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 09:56
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

Was Contact Attempted?

Yes ☒

No ☐

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

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:29 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 15:29
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3252127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	7 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:56 (24 HR)
Collection date and time (derived)	7 OCT 2020 15:56

US3252127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

14 OCT 2020 18:57:12

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

20 OCT 2020 12:18:01

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 11:38:35

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 NOV 2020 15:52:24
Patient Cloud Open Date & Time	15 NOV 2020 00:01
v6.020 DTW (1102)	
133 of 2164	

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 14:29:22

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

Patient Cloud Open Date & Time	12 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	16 AUG 2021 23:59
---	-------------------

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

Patient Cloud Open Date & Time	23 DEC 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	27 DEC 2021 23:59
---	-------------------

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

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

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

Was Contact Attempted?

Yes ☒

No ☐

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

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3252127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3252127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3252127

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:50:23

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3252127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:50:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

AEID

Adverse event

COLD INTOLERANCE

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)

14 SEP 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

Persistent or significant disability or incapacity

False

v6.020 DTW (1102)

353 of 2164

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

AEID	USA-US108-2020-MRNA-1273-P30 1000013
Adverse event	APPENDICITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	29 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	355 of 2164

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT PRESENTED WITH APPENDICITIS ON OCTOBER 28TH, GOT OPERATED THE SAME DAY AND GOT DISCHARGED ON OCTOBER 29TH.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

v6.020 DTW (1102)

356 of 2164

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:50:23

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

Yes ☒

No ☐

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

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	FENOFIBERATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTEREMIA
Dose per administration	134
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	MONTELUKAST
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	PRAVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTEROL
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	DOXAZOSIN MESYLATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	4
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	METOPROLOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERTENSION
Dose per administration	50
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	AMLODIPINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	FINISTERIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ENLARGED PROSTATE
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input checked="" type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	DICLOFENAC 1% TOPICAL GEL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	OSTEOARTHRITIS OF HANDS
Dose per administration	2
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	APPLICATIONS
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input checked="" type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	LINZESS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CONSTIPATION
Dose per administration	72
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	FLUTICASONE PROPIONATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input checked="" type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

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

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	ZOLPIDEM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INSOMNIA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	EUTHYROX
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROID
Dose per administration	50
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	MCG
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	MULTIVITAMINS
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DIETARY SUPPLEMENT
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	CAROTID ATHEROSCLEROSIS
Dose per administration	81
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	BETA SITOSTEROL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input checked="" type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GASTRITIS
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	PAIN IN INJECTION SITE
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input checked="" type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	ESOMEPRAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GASTRITIS
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	30 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	SUCRALFATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	GASTRITIS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	GENERAL HEALTH
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	INJECTION
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

Name of Medication	AMOXICILLIN/CLAVULANATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	APPENDICITIS
Dose per administration	500/125
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:50:23

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:50:23

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
28 OCT 2020	APPENDECTOMY	Adverse Event	

US3252127

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:50:23

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3252127

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:50:23

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 ☐

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

SAEID	USA-US108-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:50:23

SAEID	USA-US108-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	04/NOV/2020 12:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:50:23

SAEID	USA-US108-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOEL
Investigator's Last Name	SOLIS
Site Address: Street	5201 N. 10TH STREET
Site Address: City	MCALLEN
Site Address: State	TX
Site Address: Postal Code	CARMPA
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	23/NOV/2020 15:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3252127 (Prod: Centex Studies Inc)

US3252127

Form: Participant Creation

Generated On: 26 Nov 2020 10:50:23

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3252127'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Aug 2020 20:59:23

US3252127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:09

US3252127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Aug 2020 20:59:24

US3252127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:09

US3252127

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 22:23:09

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 20:59:25

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Age](#)

Audit	User	Time (GMT)
User entered '68'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '68'	System	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:02:37
User entered 'Female (F)'	Uche Ehiemua (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

White

Audit	User	Time (GMT)
User entered '1'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

Unknown

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:50:23

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:36

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:23:53

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 20:59:24

US3252127

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:50:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Aug 2020 22:24:05

US3252127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:50:23

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:24:05

US3252127

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:50:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:35:24

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:38:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:38:09
Data point term sent to Coder	System	12 Aug 2020 18:37:03
User entered 'Hypertension'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:37:01

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 13:42:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 13:42:22
Data point term sent to Coder	System	04 Nov 2020 13:41:24
Coding entries removed.	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 13:40:43
User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 13:40:43
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:40:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:40:19
Data point term sent to Coder	System	12 Aug 2020 18:39:13
User entered 'Enlarged Prostate'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2009'	System	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:38:35

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:41:13
Data point term sent to Coder	System	12 Aug 2020 18:40:15
User entered 'Hypercholesterolemia'	Joanna Gurrola (b) (4)	12 Aug 2020 18:39:23
	(b) (4)	

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:39:23

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Trigger finger, LLT: Trigger finger (acquired) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:36:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:36:14
Data point term sent to Coder	System	12 Aug 2020 18:40:17
User entered 'Acquired trigger finger'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2017'	System	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:39:58

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

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)	12 Aug 2020 18:42:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:42:19
Data point term sent to Coder	System	12 Aug 2020 18:41:19
User entered 'Hypothyroid'	Joanna Gurrola (b) (4)	12 Aug 2020 18:40:34
	(b) (4)	

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:40:34

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:42:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:42:20
Data point term sent to Coder	System	12 Aug 2020 18:41:20
User entered 'Asthma'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:41:04

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:44:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:44:10
Data point term sent to Coder	System	12 Aug 2020 18:43:27
User entered 'Gastritis'	Joanna Gurrola (b) (4)	12 Aug 2020 18:43:23
	(b) (4)	

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2018'	System	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:43:23

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid arteriosclerosis, LLT: Carotid arteriosclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:15:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:15:15
Data point term sent to Coder	System	12 Aug 2020 18:44:28
User entered 'Carotid atherosclerosis'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2009' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	02 Nov 2020 20:32:17
User entered 'UN Jun 2020'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	02 Nov 2020 20:32:17
User entered 'Jun 2020'	System	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2009'	System	02 Nov 2020 20:32:17
User entered '2020'	System	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:44:25

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the type (decreased brain mass, loss of neurological function) of CEREBRAL ATROPHY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:49:33
User coded data point as SOC: Nervous system disorders, HLT: Structural brain disorders, HLT: Structural brain disorders NEC, PT: Cerebral atrophy, LLT: Cerebral atrophy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:50:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:50:37
Data point term sent to Coder	System	15 Sep 2020 22:09:09
Query 'Per DM CLR: Please specify the type (decreased brain mass, loss of neurological function) of CEREBRAL ATROPHY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'As per patient, patient mentioned that he just had general cerebral atrophy. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 22:09:07
Coding entries removed.	(b) (4), (b) (6)	15 Sep 2020 22:08:43
User entered 'GENERAL CEREBRAL ATROPHY' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 22:08:43
User opened query 'Per DM CLR: Please specify the type (decreased brain mass, loss of neurological function) of CEREBRAL ATROPHY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:25:39
User coded data point as SOC: Nervous system disorders, HLT: Structural brain disorders, HLT: Structural brain disorders NEC, PT: Cerebral atrophy, LLT: Cerebral atrophy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:46:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:46:11
Data point term sent to Coder	System	12 Aug 2020 18:45:30

v6.020 DTW (1102)

520 of 2164

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

[Condition](#)

Audit	User	Time (GMT)
User entered 'Cerebral Atrophy'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN Jun 2020'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:45:30

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:48:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:48:12
Data point term sent to Coder	System	12 Aug 2020 18:47:33
User entered 'Chronic Sinusitis'	Joanna Gurrola (b) (4)	12 Aug 2020 18:46:34
	(b) (4)	

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 19:17:04
User entered 'UN UNK 2015' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:17:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 18:46:34
User entered '00 UNK 2015' (non-conformant).	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 19:17:04
User entered empty.	System	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 19:17:04
User entered empty.	System	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:46:34

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

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: Chronic idiopathic constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:48:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:48:12
Data point term sent to Coder	System	12 Aug 2020 18:47:37
User entered 'Chronic Idiopathic Constipation'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2019'	System	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:47:28

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:52:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:52:49
Data point term sent to Coder	System	12 Aug 2020 18:51:47
User entered 'CHRONIC KIDNEY DISEASE STAGE 3' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 18:51:06
Data point term sent to Coder	System	12 Aug 2020 18:49:39
User entered 'Chronic Kidnsy Disease Stage 3'	Joanna Gurrola (b) (4)	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2018'	System	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:48:42

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 21:54:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 21:16:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Oct 2020 21:16:53
Data point term sent to Coder	System	01 Oct 2020 21:15:21
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'DATA UPDATED ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 21:14:28
Coding entries removed.	(b) (4), (b) (6)	01 Oct 2020 21:14:23
User entered 'OSTEOARTHRITIS OF HANDS' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 21:14:23
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:26:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:50:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Aug 2020 18:50:19
Data point term sent to Coder	System	12 Aug 2020 18:49:42
User entered 'Osteoarthritis'	Joanna Gurrola (b) (4)	12 Aug 2020 18:49:32
	(b) (4)	

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:49:32

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:52:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 18:52:08
Data point term sent to Coder	System	12 Aug 2020 18:50:45
User entered 'Insomnia'	Joanna Gurrola (b) (4)	12 Aug 2020 18:50:02
	(b) (4)	

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2010'	System	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:50:02

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:37:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:37:19
Data point term sent to Coder	System	12 Aug 2020 18:50:46
User entered 'Vitamion D Defi'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 19:16:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 19:16:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:16:20
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 18:50:36
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2017'	System	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 18:50:36

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 21:54:45
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'INDICATION FOR THIS IS THE GASTRITIS. DATA HAS BEEN PROVIDED, THANK YOU ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 21:18:06
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:27:22
User coded data point as SOC: Investigations, HLGT: Investigations, imaging and histopathology procedures NEC, HLT: Imaging procedures NEC, PT: Endoscopy, LLT: Endoscopy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:28:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:28:26
Data point term sent to Coder	System	20 Aug 2020 19:27:43
User entered 'ENDOSCOPY'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 19:27:37

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 21:54:51
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'THIS WAS A REGULAR ROUTINE EXAM AS PER THE PATIENT. THANK YOU. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 21:18:30
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:27:46
User coded data point as SOC: Investigations, HLT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:29:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:29:19
Data point term sent to Coder	System	20 Aug 2020 19:28:46
User entered 'COLONOSCOPY'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN Aug 2018'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'UN Aug 2018'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Aug 2018'	System	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2018'	System	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Aug 2018'	System	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '2018'	System	20 Aug 2020 19:28:09

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '16:04'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:04'	System	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Height (xxx.x)

Audit	User	Time (GMT)
User entered '68.7' in	Joanna Gurrola (b) (4)	12 Aug 2020 18:54:51
DataPoint set to visible.	(b) (4) System	11 Aug 2020 22:24:05

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '199' lb	Joanna Gurrola (b) (4)	12 Aug 2020 18:54:51
DataPoint set to visible.	(b) (4) System	11 Aug 2020 22:24:05

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
Amendment Manager: User entered '29.70636'	System	16 Sep 2020 23:52:39
User entered '29.7'	System	12 Aug 2020 18:54:51
DataPoint set to visible.	System	11 Aug 2020 22:24:05

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	12 Aug 2020 18:54:51
DataPoint set to visible.	System	11 Aug 2020 22:24:05

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:24:42
User entered '98.1' F	Joanna Gurrola (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 12:36:31
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Shannon Moyer (b) (4)	20 Aug 2020 19:24:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Aug 2020 19:24:42
User entered empty; reason for change Data Entry Error	System	20 Aug 2020 19:24:42
User entered 'Oral (Oral)'	Shannon Moyer (b) (4)	20 Aug 2020 19:24:42
	(b) (4)	
	Joanna Gurrola (b) (4)	12 Aug 2020 18:54:51
	(b) (4)	

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:24:42
User entered '75'	Joanna Gurrola (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:24:42
User entered '15'	Joanna Gurrola (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:24:42
User entered '143'	Joanna Gurrola (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:24:42
User entered '73'	Joanna Gurrola (b) (4)	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Aug 2020 18:54:51

US3252127

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 18:56:32

US3252127

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 14:37:35
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		09 Sep 2020 02:55:33
User entered '11 Aug 2020'	Joanna Gurrola (b) (4)	12 Aug 2020 18:56:32
	(b) (4)	

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Was the pregnancy test performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 19:27:58

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 19:27:58

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 19:27:58

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Result](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 19:27:58

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 19:27:58

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 19:27:58

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	12 Aug 2020 19:27:58

US3252127

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 19:27:58

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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 closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:30:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 19:30:33
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	12 Aug 2020 19:30:33
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:17:59
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

[Specify](#)

Audit	User	Time (GMT)
User entered 'Retired'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:50:23

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:17:59

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:24:22

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:24:22

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:24:22

US3252127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 22:24:22

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Aug 2020 22:04:08

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

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 03:43:40
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:43:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 22:04:08
User entered '185790' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 22:04:08

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Aug 2020 22:04:08

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

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 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:25:06

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:25:06

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:25:06

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:25:06

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 22:25:06

US3252127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4)	30 Sep 2020 05:05:23
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:38:33

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:23

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:28:40
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered '68.7' in	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:23

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:28:40
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered '199' lb	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:23

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:28:40
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered '68.7' in	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:23

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	24 Aug 2020 18:28:40
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User entered '199' lb	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '16:04'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 16:04'	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 19:20:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 19:20:20
User entered '98.1' F reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 19:42:03
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 19:20:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 19:42:03
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 19:20:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 19:20:20
User entered '75' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 19:42:03
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 19:20:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 19:20:20
User entered '15' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 19:42:03
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 19:20:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 19:20:20
User entered '143' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 19:42:03
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 19:20:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 19:20:20
User entered '73' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 19:42:03
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:23

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:28:40
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered '68.7' in	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:50:23

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:28:40
User entered empty; reason for change Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered '199' lb	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 19:20:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 19:20:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 19:42:03
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 03:43:36
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per Source, correct as is' (Site from System).	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:41
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).		20 Aug 2020 19:20:20
User entered '18:24' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:20:20
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 18:24'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:36:37
Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM).	Joanna Gurrola (b) (4)	09 Oct 2020 19:22:18
User entered '97.5' F reason for change: Data Entry Error	(b) (4)	09 Oct 2020 19:20:01
User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:56:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:35:14
User entered '97.5' F reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	09 Oct 2020 19:20:01
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:35:14
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:36:41
Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM).	Joanna Gurrola (b) (4)	09 Oct 2020 19:22:20
User entered '75' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 19:20:01
User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:56:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:35:14
User entered '75' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:36:46
Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM).	Joanna Gurrola (b) (4)	09 Oct 2020 19:22:34
User entered '16' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 19:20:01
User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:56:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:35:14
User entered '16' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:36:53
Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM).	Joanna Gurrola (b) (4)	09 Oct 2020 19:22:41
User entered '155' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 19:20:01
User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:56:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:35:14
User entered '155' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:36:57
Query 'Per CDM: As per CCG, Data is required, please update accordingly.' answered with 'updated' (Site from DM).	Joanna Gurrola (b) (4)	09 Oct 2020 19:22:54
User entered '75' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 19:20:01
User opened query 'Per CDM: As per CCG, Data is required, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:56:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:35:14
User entered '75' reason for change: Data Entry Error	Shannon Moyer (b) (4)	20 Aug 2020 19:20:20
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 19:20:20
User entered empty.	System	12 Aug 2020 19:42:03

US3252127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	24 Aug 2020 18:27:31
User entered 'Yes (Y)'	Joanna Gurrola (b) (4)	12 Aug 2020 19:43:10

US3252127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	24 Aug 2020 18:27:31
User entered '11 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:43:10

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Was the pregnancy test performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:22:51

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:22:51

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:22:51

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Result](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:22:51

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:22:51

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:22:51

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:22:51

US3252127

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 19:22:51

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '17:34'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 17:34'	System	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Uche Ehiemua (b) (4) (b) (4)	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 23:07:38

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:47:08

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:47:08

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '17:16'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:47:08

US3252127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 17:16'	System	12 Aug 2020 19:47:08

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '17:00'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 17:00'	System	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 19:50:06

US3252127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:50:42

US3252127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:50:42

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:25:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'be6f3f51-86ba-4bb6-8016-8210ddc707b1'	System	11 Aug 2020 23:27:05
User entered 'Yes (Y)'	System	11 Aug 2020 23:27:05

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:25:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'be6f3f51-86ba-4bb6-8016-8210ddc707b1'	System	11 Aug 2020 23:27:05
User entered '97.5'	System	11 Aug 2020 23:27:05

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:26:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'be6f3f51-86ba-4bb6-8016-8210ddc707b1'	System	11 Aug 2020 23:27:05
User entered 'No (N)'	System	11 Aug 2020 23:27:05

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:27:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'be6f3f51-86ba-4bb6-8016-8210ddc707b1'	System	11 Aug 2020 23:27:05
User entered '11 Aug 2020 18:27'	System	11 Aug 2020 23:27:05

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 17:54'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 20:24'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:41:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6098d168-6c79-4ca0-9575-f78579489f49'	System	12 Aug 2020 16:41:49
User entered 'Yes (Y)'	System	12 Aug 2020 16:41:49

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:41:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6098d168-6c79-4ca0-9575-f78579489f49'	System	12 Aug 2020 16:41:49
User entered '97.3'	System	12 Aug 2020 16:41:49

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:41:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6098d168-6c79-4ca0-9575-f78579489f49'	System	12 Aug 2020 16:41:49
User entered 'No (N)'	System	12 Aug 2020 16:41:49

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:41:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6098d168-6c79-4ca0-9575-f78579489f49'	System	12 Aug 2020 16:41:49
User entered '12 Aug 2020 11:41'	System	12 Aug 2020 16:41:49

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 21:19'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 2'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:17:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10abd98d-b5fd-47b2-b028-85142d0e7e82'	System	13 Aug 2020 05:17:52
User entered 'Yes (Y)'	System	13 Aug 2020 05:17:52

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:17:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10abd98d-b5fd-47b2-b028-85142d0e7e82'	System	13 Aug 2020 05:17:52
User entered '97.3'	System	13 Aug 2020 05:17:52

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:17:38', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10abd98d-b5fd-47b2-b028-85142d0e7e82'	System	13 Aug 2020 05:17:52
User entered 'No (N)'	System	13 Aug 2020 05:17:52

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:17:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '10abd98d-b5fd-47b2-b028-85142d0e7e82'	System	13 Aug 2020 05:17:52
User entered '13 Aug 2020 00:17'	System	13 Aug 2020 05:17:52

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 3'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:33:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '06186ffc-fd9d-411e-b35a-a028cec19954'	System	14 Aug 2020 00:34:04
User entered 'Yes (Y)'	System	14 Aug 2020 00:34:04

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:33:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '06186ffc-fd9d-411e-b35a-a028cec19954'	System	14 Aug 2020 00:34:04
User entered '96.6'	System	14 Aug 2020 00:34:04

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:33:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '06186ffc-fd9d-411e-b35a-a028cec19954'	System	14 Aug 2020 00:34:04
User entered 'No (N)'	System	14 Aug 2020 00:34:04

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:04', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '06186ffc-fd9d-411e-b35a-a028cec19954'	System	14 Aug 2020 00:34:04
User entered '13 Aug 2020 19:34'	System	14 Aug 2020 00:34:04

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 4'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:03:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '014a9655-b936-41f6-a16b-7fd61bee4c73'	System	15 Aug 2020 01:04:12
User entered 'Yes (Y)'	System	15 Aug 2020 01:04:12

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:03:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '014a9655-b936-41f6-a16b-7fd61bee4c73'	System	15 Aug 2020 01:04:12
User entered '97.9'	System	15 Aug 2020 01:04:12

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:03:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '014a9655-b936-41f6-a16b-7fd61bee4c73'	System	15 Aug 2020 01:04:12
User entered 'No (N)'	System	15 Aug 2020 01:04:12

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:04:14', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '014a9655-b936-41f6-a16b-7fd61bee4c73'	System	15 Aug 2020 01:04:12
User entered '14 Aug 2020 20:04'	System	15 Aug 2020 01:04:12

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 5'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:29:57', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '940cb0bd-a927-46b8-9b26-8937487bd1be'	System	16 Aug 2020 04:30:31
User entered 'Yes (Y)'	System	16 Aug 2020 04:30:31

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:14', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '940cb0bd-a927-46b8-9b26-8937487bd1be'	System	16 Aug 2020 04:30:31
User entered '97.6'	System	16 Aug 2020 04:30:31

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '940cb0bd-a927-46b8-9b26-8937487bd1be'	System	16 Aug 2020 04:30:31
User entered 'No (N)'	System	16 Aug 2020 04:30:31

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '940cb0bd-a927-46b8-9b26-8937487bd1be'	System	16 Aug 2020 04:30:31
User entered '15 Aug 2020 23:30'	System	16 Aug 2020 04:30:31

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 6'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:11', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4a9360fc-5dc9-4477-95cb-31f5dc9a27b5'	System	17 Aug 2020 03:08:36
User entered 'Yes (Y)'	System	17 Aug 2020 03:08:36

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4a9360fc-5dc9-4477-95cb-31f5dc9a27b5'	System	17 Aug 2020 03:08:36
User entered '97.6'	System	17 Aug 2020 03:08:36

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:24', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4a9360fc-5dc9-4477-95cb-31f5dc9a27b5'	System	17 Aug 2020 03:08:36
User entered 'No (N)'	System	17 Aug 2020 03:08:36

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4a9360fc-5dc9-4477-95cb-31f5dc9a27b5'	System	17 Aug 2020 03:08:36
User entered '16 Aug 2020 22:08'	System	17 Aug 2020 03:08:36

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 7'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:56:39', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7f161c37-26f5-487b-968e-7e8e451f68ce'	System	18 Aug 2020 00:57:02
User entered 'Yes (Y)'	System	18 Aug 2020 00:57:02

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:56:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7f161c37-26f5-487b-968e-7e8e451f68ce'	System	18 Aug 2020 00:57:02
User entered '97.7'	System	18 Aug 2020 00:57:02

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:56:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7f161c37-26f5-487b-968e-7e8e451f68ce'	System	18 Aug 2020 00:57:02
User entered 'No (N)'	System	18 Aug 2020 00:57:02

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:57:01', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7f161c37-26f5-487b-968e-7e8e451f68ce'	System	18 Aug 2020 00:57:02
User entered '17 Aug 2020 19:57'	System	18 Aug 2020 00:57:02

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-11T18:35:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb'	System	11 Aug 2020 23:35:23
User entered 'None (1)'	System	11 Aug 2020 23:35:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:09', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb'	System	11 Aug 2020 23:35:23
User entered 'No (N)'	System	11 Aug 2020 23:35:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb'	System	11 Aug 2020 23:35:23
User entered 'No (N)'	System	11 Aug 2020 23:35:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-11T18:35:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb'	System	11 Aug 2020 23:35:23
User entered 'None (1)'	System	11 Aug 2020 23:35:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '88e7a31c-30c6-4397-8b97-d1174058c9eb'	System	11 Aug 2020 23:35:23
User entered '11 Aug 2020 18:35'	System	11 Aug 2020 23:35:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 17:54'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 20:24'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-12T11:42:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8'	System	12 Aug 2020 16:43:54
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 16:43:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8'	System	12 Aug 2020 16:43:54
User entered 'No (N)'	System	12 Aug 2020 16:43:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8'	System	12 Aug 2020 16:43:54
User entered 'No (N)'	System	12 Aug 2020 16:43:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-12T11:43:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8'	System	12 Aug 2020 16:43:54
User entered 'None (1)'	System	12 Aug 2020 16:43:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ce7efdd1-1149-4de5-a2ee-3309647a4ea8'	System	12 Aug 2020 16:43:54
User entered '12 Aug 2020 11:43'	System	12 Aug 2020 16:43:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 21:19'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 2'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-13T00:18:14', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4'	System	13 Aug 2020 05:18:54
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 05:18:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4'	System	13 Aug 2020 05:18:54
User entered 'No (N)'	System	13 Aug 2020 05:18:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4'	System	13 Aug 2020 05:18:54
User entered 'No (N)'	System	13 Aug 2020 05:18:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-13T00:18:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4'	System	13 Aug 2020 05:18:54
User entered 'None (1)'	System	13 Aug 2020 05:18:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4f03cc91-9698-4428-ae75-872d08be38a4'	System	13 Aug 2020 05:18:54
User entered '13 Aug 2020 00:18'	System	13 Aug 2020 05:18:54

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 3'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-13T19:34:19', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed'	System	14 Aug 2020 00:34:42
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 00:34:42

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed'	System	14 Aug 2020 00:34:42
User entered 'No (N)'	System	14 Aug 2020 00:34:42

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:26', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed'	System	14 Aug 2020 00:34:42
User entered 'No (N)'	System	14 Aug 2020 00:34:42

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-13T19:34:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed'	System	14 Aug 2020 00:34:42
User entered 'None (1)'	System	14 Aug 2020 00:34:42

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3ae99b12-236c-40f5-b596-95c1c562d4ed'	System	14 Aug 2020 00:34:42
User entered '13 Aug 2020 19:34'	System	14 Aug 2020 00:34:42

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 4'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-14T20:04:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e'	System	15 Aug 2020 01:05:04
User entered 'None (1)'	System	15 Aug 2020 01:05:04

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:04:39', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e'	System	15 Aug 2020 01:05:04
User entered 'No (N)'	System	15 Aug 2020 01:05:04

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:04:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e'	System	15 Aug 2020 01:05:04
User entered 'No (N)'	System	15 Aug 2020 01:05:04

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-14T20:04:54', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e'	System	15 Aug 2020 01:05:04
User entered 'None (1)'	System	15 Aug 2020 01:05:04

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2cca1f2e-84f8-4538-bd12-8c07d152637e'	System	15 Aug 2020 01:05:04
User entered '14 Aug 2020 20:05'	System	15 Aug 2020 01:05:04

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 5'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-15T23:30:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41'	System	16 Aug 2020 04:31:08
User entered 'None (1)'	System	16 Aug 2020 04:31:08

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:44', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41'	System	16 Aug 2020 04:31:08
User entered 'No (N)'	System	16 Aug 2020 04:31:08

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:30:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41'	System	16 Aug 2020 04:31:08
User entered 'No (N)'	System	16 Aug 2020 04:31:08

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-15T23:30:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41'	System	16 Aug 2020 04:31:08
User entered 'None (1)'	System	16 Aug 2020 04:31:08

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:04', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3d292382-ae6d-4214-b9d4-ec43f6ae0d41'	System	16 Aug 2020 04:31:08
User entered '15 Aug 2020 23:31'	System	16 Aug 2020 04:31:08

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 6'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-16T22:08:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e'	System	17 Aug 2020 03:09:18
User entered 'None (1)'	System	17 Aug 2020 03:09:18

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:08:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e'	System	17 Aug 2020 03:09:18
User entered 'No (N)'	System	17 Aug 2020 03:09:18

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e'	System	17 Aug 2020 03:09:18
User entered 'No (N)'	System	17 Aug 2020 03:09:18

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-16T22:09:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e'	System	17 Aug 2020 03:09:18
User entered 'None (1)'	System	17 Aug 2020 03:09:18

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:16', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '2ce74553-d4b1-46c4-9842-a8c456a18a5e'	System	17 Aug 2020 03:09:18
User entered '16 Aug 2020 22:09'	System	17 Aug 2020 03:09:18

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 7'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-17T19:58:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce'	System	18 Aug 2020 00:58:23
User entered 'None (1)'	System	18 Aug 2020 00:58:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce'	System	18 Aug 2020 00:58:23
User entered 'No (N)'	System	18 Aug 2020 00:58:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce'	System	18 Aug 2020 00:58:23
User entered 'No (N)'	System	18 Aug 2020 00:58:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-17T19:58:16', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce'	System	18 Aug 2020 00:58:23
User entered 'None (1)'	System	18 Aug 2020 00:58:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '152478a4-5aa5-4c9d-bbf2-b739cf05f6ce'	System	18 Aug 2020 00:58:23
User entered '17 Aug 2020 19:58'	System	18 Aug 2020 00:58:23

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e'	System	11 Aug 2020 23:35:48
User entered 'None (0)'	System	11 Aug 2020 23:35:48

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e'	System	11 Aug 2020 23:35:48
User entered 'None (0)'	System	11 Aug 2020 23:35:48

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e'	System	11 Aug 2020 23:35:48
User entered 'None (0)'	System	11 Aug 2020 23:35:48

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e'	System	11 Aug 2020 23:35:48
User entered 'None (0)'	System	11 Aug 2020 23:35:48

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e'	System	11 Aug 2020 23:35:48
User entered 'None (0)'	System	11 Aug 2020 23:35:48

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e'	System	11 Aug 2020 23:35:48
User entered 'None (0)'	System	11 Aug 2020 23:35:48

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-11T18:35:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e'	System	11 Aug 2020 23:35:48
User entered 'No (N)'	System	11 Aug 2020 23:35:48

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-11T18:35:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'acdf26f4-0624-4fb9-8041-b0eb6974e24e'	System	11 Aug 2020 23:35:48
User entered '11 Aug 2020 18:35'	System	11 Aug 2020 23:35:48

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 17:54'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 20:24'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0'	System	12 Aug 2020 16:44:55
User entered 'None (0)'	System	12 Aug 2020 16:44:55

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:50', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0'	System	12 Aug 2020 16:44:55
User entered 'None (0)'	System	12 Aug 2020 16:44:55

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:43:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0'	System	12 Aug 2020 16:44:55
User entered 'None (0)'	System	12 Aug 2020 16:44:55

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:00', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0'	System	12 Aug 2020 16:44:55
User entered 'None (0)'	System	12 Aug 2020 16:44:55

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:04', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0'	System	12 Aug 2020 16:44:55
User entered 'None (0)'	System	12 Aug 2020 16:44:55

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0'	System	12 Aug 2020 16:44:55
User entered 'None (0)'	System	12 Aug 2020 16:44:55

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-12T11:44:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0'	System	12 Aug 2020 16:44:55
User entered 'No (N)'	System	12 Aug 2020 16:44:55

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-12T11:44:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7bbff10f-35d0-4209-b67a-84c38432b4e0'	System	12 Aug 2020 16:44:55
User entered '12 Aug 2020 11:44'	System	12 Aug 2020 16:44:55

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 21:19'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 2'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:18:57', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1'	System	13 Aug 2020 05:19:49
User entered 'None (0)'	System	13 Aug 2020 05:19:49

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1'	System	13 Aug 2020 05:19:49
User entered 'None (0)'	System	13 Aug 2020 05:19:49

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1'	System	13 Aug 2020 05:19:49
User entered 'None (0)'	System	13 Aug 2020 05:19:49

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1'	System	13 Aug 2020 05:19:49
User entered 'None (0)'	System	13 Aug 2020 05:19:49

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1'	System	13 Aug 2020 05:19:49
User entered 'None (0)'	System	13 Aug 2020 05:19:49

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1'	System	13 Aug 2020 05:19:49
User entered 'None (0)'	System	13 Aug 2020 05:19:49

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-13T00:19:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1'	System	13 Aug 2020 05:19:49
User entered 'No (N)'	System	13 Aug 2020 05:19:49

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T00:19:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '9a2d332e-d6a4-4972-91d0-3b63b121cfc1'	System	13 Aug 2020 05:19:49
User entered '13 Aug 2020 00:19'	System	13 Aug 2020 05:19:49

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 3'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:34:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd'	System	14 Aug 2020 00:36:04
User entered 'None (0)'	System	14 Aug 2020 00:36:04

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:19', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd'	System	14 Aug 2020 00:36:04
User entered 'None (0)'	System	14 Aug 2020 00:36:04

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd'	System	14 Aug 2020 00:36:04
User entered 'None (0)'	System	14 Aug 2020 00:36:04

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd'	System	14 Aug 2020 00:36:04
User entered 'None (0)'	System	14 Aug 2020 00:36:04

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd'	System	14 Aug 2020 00:36:04
User entered 'None (0)'	System	14 Aug 2020 00:36:04

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:35:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd'	System	14 Aug 2020 00:36:04
User entered 'None (0)'	System	14 Aug 2020 00:36:04

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-13T19:35:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd'	System	14 Aug 2020 00:36:04
User entered 'No (N)'	System	14 Aug 2020 00:36:04

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-13T19:36:04', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '98c82b4b-7648-4f30-938c-ba8c826adabd'	System	14 Aug 2020 00:36:04
User entered '13 Aug 2020 19:36'	System	14 Aug 2020 00:36:04

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 4'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7'	System	15 Aug 2020 01:05:47
User entered 'None (0)'	System	15 Aug 2020 01:05:47

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7'	System	15 Aug 2020 01:05:47
User entered 'None (0)'	System	15 Aug 2020 01:05:47

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7'	System	15 Aug 2020 01:05:47
User entered 'None (0)'	System	15 Aug 2020 01:05:47

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:26', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7'	System	15 Aug 2020 01:05:47
User entered 'None (0)'	System	15 Aug 2020 01:05:47

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7'	System	15 Aug 2020 01:05:47
User entered 'None (0)'	System	15 Aug 2020 01:05:47

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7'	System	15 Aug 2020 01:05:47
User entered 'None (0)'	System	15 Aug 2020 01:05:47

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-14T20:05:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7'	System	15 Aug 2020 01:05:47
User entered 'No (N)'	System	15 Aug 2020 01:05:47

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-14T20:05:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '03b82527-5c42-4e6f-be26-4b00208311d7'	System	15 Aug 2020 01:05:47
User entered '14 Aug 2020 20:05'	System	15 Aug 2020 01:05:47

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 5'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1'	System	16 Aug 2020 04:32:01
User entered 'None (0)'	System	16 Aug 2020 04:32:01

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1'	System	16 Aug 2020 04:32:01
User entered 'None (0)'	System	16 Aug 2020 04:32:01

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:23', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1'	System	16 Aug 2020 04:32:01
User entered 'None (0)'	System	16 Aug 2020 04:32:01

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1'	System	16 Aug 2020 04:32:01
User entered 'None (0)'	System	16 Aug 2020 04:32:01

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1'	System	16 Aug 2020 04:32:01
User entered 'None (0)'	System	16 Aug 2020 04:32:01

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:37', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1'	System	16 Aug 2020 04:32:01
User entered 'None (0)'	System	16 Aug 2020 04:32:01

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-15T23:31:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1'	System	16 Aug 2020 04:32:01
User entered 'No (N)'	System	16 Aug 2020 04:32:01

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-15T23:31:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e9deb329-2b67-47a1-af7e-4f0c681e99b1'	System	16 Aug 2020 04:32:01
User entered '15 Aug 2020 23:31'	System	16 Aug 2020 04:32:01

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 6'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f'	System	17 Aug 2020 03:09:51
User entered 'None (0)'	System	17 Aug 2020 03:09:51

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f'	System	17 Aug 2020 03:09:51
User entered 'None (0)'	System	17 Aug 2020 03:09:51

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f'	System	17 Aug 2020 03:09:51
User entered 'None (0)'	System	17 Aug 2020 03:09:51

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f'	System	17 Aug 2020 03:09:51
User entered 'None (0)'	System	17 Aug 2020 03:09:51

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f'	System	17 Aug 2020 03:09:51
User entered 'None (0)'	System	17 Aug 2020 03:09:51

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:37', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f'	System	17 Aug 2020 03:09:51
User entered 'None (0)'	System	17 Aug 2020 03:09:51

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-16T22:09:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f'	System	17 Aug 2020 03:09:51
User entered 'No (N)'	System	17 Aug 2020 03:09:51

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-16T22:09:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b02b6d24-c179-4c44-a086-828fb899368f'	System	17 Aug 2020 03:09:51
User entered '16 Aug 2020 22:09'	System	17 Aug 2020 03:09:51

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 7'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed'	System	18 Aug 2020 00:59:19
User entered 'None (0)'	System	18 Aug 2020 00:59:19

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:39', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed'	System	18 Aug 2020 00:59:19
User entered 'None (0)'	System	18 Aug 2020 00:59:19

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed'	System	18 Aug 2020 00:59:19
User entered 'None (0)'	System	18 Aug 2020 00:59:19

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed'	System	18 Aug 2020 00:59:19
User entered 'None (0)'	System	18 Aug 2020 00:59:19

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed'	System	18 Aug 2020 00:59:19
User entered 'None (0)'	System	18 Aug 2020 00:59:19

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:58:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed'	System	18 Aug 2020 00:59:19
User entered 'None (0)'	System	18 Aug 2020 00:59:19

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-08-17T19:59:08', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed'	System	18 Aug 2020 00:59:19
User entered 'No (N)'	System	18 Aug 2020 00:59:19

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-08-17T19:59:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3463d7ce-828e-49cc-a634-96bfaef008ed'	System	18 Aug 2020 00:59:19
User entered '17 Aug 2020 19:59'	System	18 Aug 2020 00:59:19

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 23:07:38

US3252127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:30:50

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:30:50

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:30:50

US3252127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:30:50

US3252127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:31:09

US3252127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Aug 2020 19:31:09

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 16:26:07

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 16:26:07

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 16:26:07

US3252127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 16:26:07

US3252127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	26 Aug 2020 16:26:14

US3252127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Aug 2020 16:26:14

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:33:29

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '01 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:33:29

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:33:29

US3252127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:33:29

US3252127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	02 Sep 2020 21:33:34

US3252127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 21:33:34

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:55:33

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:55:33

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:55:33

US3252127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Sep 2020 02:55:33

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '15:39'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 15:39'	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '16'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '67'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:50:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '16:41'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 16:41'	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:59:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Sep 2020 02:59:55
User entered 'Oral (Oral)' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Sep 2020 02:59:55
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:58:44
User entered empty.	Shannon Moyer (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:59:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Sep 2020 02:59:55
User entered '69' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:59:55
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:58:44
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Sep 2020 02:59:55
User entered empty.	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:59:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Sep 2020 02:59:55
User entered '15' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Sep 2020 02:59:55
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:58:44
User entered empty.	Shannon Moyer (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Sep 2020 02:59:55
User entered empty.	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:59:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Sep 2020 02:59:55
User entered '128' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:59:55
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:58:44
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 02:59:55
User entered empty.	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:59:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Sep 2020 02:59:55
User entered '66' reason for change: Data Entry Error	Shannon Moyer (b) (4)	09 Sep 2020 02:59:55
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 02:58:44
User entered empty.	Shannon Moyer (b) (4)	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:50:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 02:59:55
User entered empty.	System	09 Sep 2020 02:58:44

US3252127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:00:18

US3252127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:00:18

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Was the pregnancy test performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	09 Sep 2020 13:05:04

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	09 Sep 2020 13:05:04

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	09 Sep 2020 13:05:04

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Result](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	09 Sep 2020 13:05:04

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	09 Sep 2020 13:05:04

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	09 Sep 2020 13:05:04

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	09 Sep 2020 13:05:04

US3252127

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 13:05:04

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 03:00:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 03:00:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:00:42
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 21:18:21
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 03:00:42
User entered empty.	System	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Joanna Gurrola (b) (4) (b) (4)	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '16:09'	Joanna Gurrola (b) (4) (b) (4)	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 16:09'	System	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Joanna Gurrola (b) (4) (b) (4)	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Sep 2020 03:00:42
User entered empty.	System	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:50:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 03:00:42
User entered empty.	System	08 Sep 2020 21:18:21

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:01:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:01:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:06'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:01:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 16:06'	System	09 Sep 2020 03:01:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:50:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:00'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 16:00'	System	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:23

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 03:02:31

US3252127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:02:39

US3252127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 03:02:39

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:26', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '24d1d5f7-632e-43ca-8732-f56945948d4a'	System	08 Sep 2020 21:44:42
User entered 'Yes (Y)'	System	08 Sep 2020 21:44:42

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:32', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '24d1d5f7-632e-43ca-8732-f56945948d4a'	System	08 Sep 2020 21:44:42
User entered '98.1'	System	08 Sep 2020 21:44:42

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '24d1d5f7-632e-43ca-8732-f56945948d4a'	System	08 Sep 2020 21:44:42
User entered 'No (N)'	System	08 Sep 2020 21:44:42

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:44:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '24d1d5f7-632e-43ca-8732-f56945948d4a'	System	08 Sep 2020 21:44:42
User entered '08 Sep 2020 16:44'	System	08 Sep 2020 21:44:42

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 16:29'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 18:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:46:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ba1520cd-e166-41e1-8115-025eef1e78a2'	System	09 Sep 2020 05:47:05
User entered 'Yes (Y)'	System	09 Sep 2020 05:47:05

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:46:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ba1520cd-e166-41e1-8115-025eef1e78a2'	System	09 Sep 2020 05:47:05
User entered '97.0'	System	09 Sep 2020 05:47:05

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:46:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ba1520cd-e166-41e1-8115-025eef1e78a2'	System	09 Sep 2020 05:47:05
User entered 'No (N)'	System	09 Sep 2020 05:47:05

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:47:03', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'ba1520cd-e166-41e1-8115-025eef1e78a2'	System	09 Sep 2020 05:47:05
User entered '09 Sep 2020 00:47'	System	09 Sep 2020 05:47:05

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 19:54'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 2'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:57:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb'	System	10 Sep 2020 02:58:14
User entered 'Yes (Y)'	System	10 Sep 2020 02:58:14

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:57:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb'	System	10 Sep 2020 02:58:14
User entered '98.9'	System	10 Sep 2020 02:58:14

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:57:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb'	System	10 Sep 2020 02:58:14
User entered 'Yes (Y)'	System	10 Sep 2020 02:58:14

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 'Participant was contacted to confirm new medication details. Medication was added to concomitant medication list. Thank you.	(b) (4), (b) (6)	30 Oct 2020 13:51:18
' (Site from System).		
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).	System	10 Sep 2020 02:58:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb'	System	10 Sep 2020 02:58:14
User entered '1'	System	10 Sep 2020 02:58:14

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Participant was contacted to confirm new medication details. Medication was added to concomitant medication list. Thank you.'	(b) (4), (b) (6)	30 Oct 2020 13:51:22
' (Site from System). User opened query 'Per the participant response, medication was taken to prevent 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).	System	10 Sep 2020 02:58:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb'	System	10 Sep 2020 02:58:14
User entered '1'	System	10 Sep 2020 02:58:14

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:16', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '05c2e67b-e572-4a51-9200-017c9bb253fb'	System	10 Sep 2020 02:58:14
User entered '09 Sep 2020 21:58'	System	10 Sep 2020 02:58:14

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 3'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396'	System	11 Sep 2020 14:45:55
User entered 'Yes (Y)'	System	11 Sep 2020 14:45:55

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396'	System	11 Sep 2020 14:45:55
User entered '97.0'	System	11 Sep 2020 14:45:55

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396'	System	11 Sep 2020 14:45:55
User entered 'Yes (Y)'	System	11 Sep 2020 14:45:55

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 'AS DOCUMENTED THE PATIENT TOOK TYLENOL FOR PAIN ' (Site from System).	(b) (4), (b) (6)	31 Oct 2020 10:41:03
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).	System	11 Sep 2020 14:45:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396'	System	11 Sep 2020 14:45:55
User entered '1'	System	11 Sep 2020 14:45:55

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396'	System	11 Sep 2020 14:45:55
User entered '0'	System	11 Sep 2020 14:45:55

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:45:54', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c4c10bb-6215-4135-97f0-54639de58396'	System	11 Sep 2020 14:45:55
User entered '11 Sep 2020 09:45'	System	11 Sep 2020 14:45:55

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 4'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:38', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4b1d48a8-0bfd-4d83-95d4-56f02e646428'	System	12 Sep 2020 15:32:52
User entered 'Yes (Y)'	System	12 Sep 2020 15:32:52

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4b1d48a8-0bfd-4d83-95d4-56f02e646428'	System	12 Sep 2020 15:32:52
User entered '96.1'	System	12 Sep 2020 15:32:52

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4b1d48a8-0bfd-4d83-95d4-56f02e646428'	System	12 Sep 2020 15:32:52
User entered 'No (N)'	System	12 Sep 2020 15:32:52

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '4b1d48a8-0bfd-4d83-95d4-56f02e646428'	System	12 Sep 2020 15:32:52
User entered '12 Sep 2020 10:32'	System	12 Sep 2020 15:32:52

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 5'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:26:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '53461583-b8fb-472c-b315-0e330c094292'	System	13 Sep 2020 07:27:59
User entered 'Yes (Y)'	System	13 Sep 2020 07:27:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:26:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '53461583-b8fb-472c-b315-0e330c094292'	System	13 Sep 2020 07:27:59
User entered '96.4'	System	13 Sep 2020 07:27:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:26:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '53461583-b8fb-472c-b315-0e330c094292'	System	13 Sep 2020 07:27:59
User entered 'No (N)'	System	13 Sep 2020 07:27:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:00', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '53461583-b8fb-472c-b315-0e330c094292'	System	13 Sep 2020 07:27:59
User entered '13 Sep 2020 02:28'	System	13 Sep 2020 07:27:59

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 6'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 7'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '13f92f6e-6833-4a19-90b5-bc21b7c6d8f9'	System	15 Sep 2020 14:55:33
User entered 'Yes (Y)'	System	15 Sep 2020 14:55:33

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:24', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '13f92f6e-6833-4a19-90b5-bc21b7c6d8f9'	System	15 Sep 2020 14:55:33
User entered '97.0'	System	15 Sep 2020 14:55:33

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '13f92f6e-6833-4a19-90b5-bc21b7c6d8f9'	System	15 Sep 2020 14:55:33
User entered 'No (N)'	System	15 Sep 2020 14:55:33

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '13f92f6e-6833-4a19-90b5-bc21b7c6d8f9'	System	15 Sep 2020 14:55:33
User entered '15 Sep 2020 09:55'	System	15 Sep 2020 14:55:33

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-08T16:44:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c'	System	08 Sep 2020 21:45:16
User entered 'None (1)'	System	08 Sep 2020 21:45:16

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:03', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c'	System	08 Sep 2020 21:45:16
User entered 'No (N)'	System	08 Sep 2020 21:45:16

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:06', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c'	System	08 Sep 2020 21:45:16
User entered 'No (N)'	System	08 Sep 2020 21:45:16

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-08T16:45:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c'	System	08 Sep 2020 21:45:16
User entered 'None (1)'	System	08 Sep 2020 21:45:16

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:16', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b21119bc-41b5-40a5-b25e-5df717a5547c'	System	08 Sep 2020 21:45:16
User entered '08 Sep 2020 16:45'	System	08 Sep 2020 21:45:16

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 16:29'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 18:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-09T00:47:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0'	System	09 Sep 2020 05:48:32
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 05:48:32

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:47:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0'	System	09 Sep 2020 05:48:32
User entered 'No (N)'	System	09 Sep 2020 05:48:32

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:47:58', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0'	System	09 Sep 2020 05:48:32
User entered 'No (N)'	System	09 Sep 2020 05:48:32

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-09T00:48:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0'	System	09 Sep 2020 05:48:32
User entered 'None (1)'	System	09 Sep 2020 05:48:32

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6630fa1b-bc66-4ad1-96ab-924aab9fd7c0'	System	09 Sep 2020 05:48:32
User entered '09 Sep 2020 00:48'	System	09 Sep 2020 05:48:32

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 19:54'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 2'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-09T21:58:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa'	System	10 Sep 2020 02:59:01
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 02:59:01

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa'	System	10 Sep 2020 02:59:01
User entered 'No (N)'	System	10 Sep 2020 02:59:01

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa'	System	10 Sep 2020 02:59:01
User entered 'No (N)'	System	10 Sep 2020 02:59:01

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-09T21:58:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa'	System	10 Sep 2020 02:59:01
User entered 'None (1)'	System	10 Sep 2020 02:59:01

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:58:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '3675b0a5-ed72-49c5-b099-9406f01a69fa'	System	10 Sep 2020 02:59:01
User entered '09 Sep 2020 21:58'	System	10 Sep 2020 02:59:01

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 3'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-11T09:46:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d'	System	11 Sep 2020 14:46:25
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 14:46:25

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d'	System	11 Sep 2020 14:46:25
User entered 'No (N)'	System	11 Sep 2020 14:46:25

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d'	System	11 Sep 2020 14:46:25
User entered 'No (N)'	System	11 Sep 2020 14:46:25

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-11T09:46:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d'	System	11 Sep 2020 14:46:25
User entered 'None (1)'	System	11 Sep 2020 14:46:25

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:24', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'fd036c1b-f8d5-4e5c-a6c0-a215f6f6e87d'	System	11 Sep 2020 14:46:25
User entered '11 Sep 2020 09:46'	System	11 Sep 2020 14:46:25

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 4'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-12T10:33:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437'	System	12 Sep 2020 15:33:49
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 15:33:49

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:32', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437'	System	12 Sep 2020 15:33:49
User entered 'No (N)'	System	12 Sep 2020 15:33:49

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437'	System	12 Sep 2020 15:33:49
User entered 'No (N)'	System	12 Sep 2020 15:33:49

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-12T10:33:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437'	System	12 Sep 2020 15:33:49
User entered 'None (1)'	System	12 Sep 2020 15:33:49

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '725e4274-6f0b-45fe-8756-8b9d8f277437'	System	12 Sep 2020 15:33:49
User entered '12 Sep 2020 10:33'	System	12 Sep 2020 15:33:49

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 5'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-13T02:28:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337'	System	13 Sep 2020 07:28:36
User entered 'None (1)'	System	13 Sep 2020 07:28:36

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337'	System	13 Sep 2020 07:28:36
User entered 'No (N)'	System	13 Sep 2020 07:28:36

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:18', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337'	System	13 Sep 2020 07:28:36
User entered 'No (N)'	System	13 Sep 2020 07:28:36

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-13T02:28:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337'	System	13 Sep 2020 07:28:36
User entered 'None (1)'	System	13 Sep 2020 07:28:36

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '599ed83f-43af-445a-92a1-afc1915bd337'	System	13 Sep 2020 07:28:36
User entered '13 Sep 2020 02:28'	System	13 Sep 2020 07:28:36

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 6'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 7'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-15T09:55:39', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54'	System	15 Sep 2020 14:55:59
User entered 'None (1)'	System	15 Sep 2020 14:55:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54'	System	15 Sep 2020 14:55:59
User entered 'No (N)'	System	15 Sep 2020 14:55:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:55:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54'	System	15 Sep 2020 14:55:59
User entered 'No (N)'	System	15 Sep 2020 14:55:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-15T09:55:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54'	System	15 Sep 2020 14:55:59
User entered 'None (1)'	System	15 Sep 2020 14:55:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '801c192a-73ee-45d4-bc81-35686782ab54'	System	15 Sep 2020 14:55:59
User entered '15 Sep 2020 09:56'	System	15 Sep 2020 14:55:59

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308'	System	08 Sep 2020 21:45:51
User entered 'None (0)'	System	08 Sep 2020 21:45:51

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308'	System	08 Sep 2020 21:45:51
User entered 'None (0)'	System	08 Sep 2020 21:45:51

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:30', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308'	System	08 Sep 2020 21:45:51
User entered 'None (0)'	System	08 Sep 2020 21:45:51

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308'	System	08 Sep 2020 21:45:51
User entered 'None (0)'	System	08 Sep 2020 21:45:51

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308'	System	08 Sep 2020 21:45:51
User entered 'None (0)'	System	08 Sep 2020 21:45:51

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:38', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308'	System	08 Sep 2020 21:45:51
User entered 'None (0)'	System	08 Sep 2020 21:45:51

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-08T16:45:44', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308'	System	08 Sep 2020 21:45:51
User entered 'No (N)'	System	08 Sep 2020 21:45:51

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-08T16:45:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b6b437ee-9ddb-4d5f-bf0f-0c8e58b7a308'	System	08 Sep 2020 21:45:51
User entered '08 Sep 2020 16:45'	System	08 Sep 2020 21:45:51

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 16:29'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 18:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc'	System	09 Sep 2020 05:49:06
User entered 'None (0)'	System	09 Sep 2020 05:49:06

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:40', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc'	System	09 Sep 2020 05:49:06
User entered 'None (0)'	System	09 Sep 2020 05:49:06

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:45', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc'	System	09 Sep 2020 05:49:06
User entered 'None (0)'	System	09 Sep 2020 05:49:06

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc'	System	09 Sep 2020 05:49:06
User entered 'None (0)'	System	09 Sep 2020 05:49:06

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:52', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc'	System	09 Sep 2020 05:49:06
User entered 'None (0)'	System	09 Sep 2020 05:49:06

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:48:55', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc'	System	09 Sep 2020 05:49:06
User entered 'None (0)'	System	09 Sep 2020 05:49:06

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-09T00:49:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc'	System	09 Sep 2020 05:49:06
User entered 'No (N)'	System	09 Sep 2020 05:49:06

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T00:49:06', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'bce0c0a7-6b54-4ff8-8865-67f1b9ef66bc'	System	09 Sep 2020 05:49:06
User entered '09 Sep 2020 00:49'	System	09 Sep 2020 05:49:06

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 19:54'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 2'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:05', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a'	System	10 Sep 2020 03:00:05
User entered 'None (0)'	System	10 Sep 2020 03:00:05

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:21', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a'	System	10 Sep 2020 03:00:05
User entered 'None (0)'	System	10 Sep 2020 03:00:05

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:28', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a'	System	10 Sep 2020 03:00:05
User entered 'None (0)'	System	10 Sep 2020 03:00:05

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:31', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a'	System	10 Sep 2020 03:00:05
User entered 'None (0)'	System	10 Sep 2020 03:00:05

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:34', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a'	System	10 Sep 2020 03:00:05
User entered 'None (0)'	System	10 Sep 2020 03:00:05

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T21:59:46', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a'	System	10 Sep 2020 03:00:05
User entered 'No interference with activity (1)'	System	10 Sep 2020 03:00:05

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-09T21:59:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a'	System	10 Sep 2020 03:00:05
User entered 'No (N)'	System	10 Sep 2020 03:00:05

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-09T22:00:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '192844a8-81a2-427d-882c-92877bf6be4a'	System	10 Sep 2020 03:00:05
User entered '09 Sep 2020 22:00'	System	10 Sep 2020 03:00:05

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 3'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022'	System	11 Sep 2020 14:47:24
User entered 'None (0)'	System	11 Sep 2020 14:47:24

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:36', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022'	System	11 Sep 2020 14:47:24
User entered 'No interference with activity (1)'	System	11 Sep 2020 14:47:24

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022'	System	11 Sep 2020 14:47:24
User entered 'None (0)'	System	11 Sep 2020 14:47:24

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022'	System	11 Sep 2020 14:47:24
User entered 'None (0)'	System	11 Sep 2020 14:47:24

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:46:53', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022'	System	11 Sep 2020 14:47:24
User entered 'None (0)'	System	11 Sep 2020 14:47:24

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:47:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022'	System	11 Sep 2020 14:47:24
User entered 'None (0)'	System	11 Sep 2020 14:47:24

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-11T09:47:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022'	System	11 Sep 2020 14:47:24
User entered 'No (N)'	System	11 Sep 2020 14:47:24

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-11T09:47:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '76f2b6f3-facf-4e6d-ba3f-763cb7bb3022'	System	11 Sep 2020 14:47:24
User entered '11 Sep 2020 09:47'	System	11 Sep 2020 14:47:24

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 4'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424'	System	12 Sep 2020 15:33:18
User entered 'None (0)'	System	12 Sep 2020 15:33:18

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:32:59', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424'	System	12 Sep 2020 15:33:18
User entered 'None (0)'	System	12 Sep 2020 15:33:18

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:01', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424'	System	12 Sep 2020 15:33:18
User entered 'None (0)'	System	12 Sep 2020 15:33:18

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:03', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424'	System	12 Sep 2020 15:33:18
User entered 'None (0)'	System	12 Sep 2020 15:33:18

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:06', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424'	System	12 Sep 2020 15:33:18
User entered 'None (0)'	System	12 Sep 2020 15:33:18

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424'	System	12 Sep 2020 15:33:18
User entered 'None (0)'	System	12 Sep 2020 15:33:18

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-12T10:33:11', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424'	System	12 Sep 2020 15:33:18
User entered 'No (N)'	System	12 Sep 2020 15:33:18

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-12T10:33:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'b5dc5c15-0205-4db4-8b4c-bcb30d8ba424'	System	12 Sep 2020 15:33:18
User entered '12 Sep 2020 10:33'	System	12 Sep 2020 15:33:18

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 5'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:42', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1'	System	13 Sep 2020 07:29:09
User entered 'None (0)'	System	13 Sep 2020 07:29:09

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:44', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1'	System	13 Sep 2020 07:29:09
User entered 'None (0)'	System	13 Sep 2020 07:29:09

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:47', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1'	System	13 Sep 2020 07:29:09
User entered 'None (0)'	System	13 Sep 2020 07:29:09

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:49', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1'	System	13 Sep 2020 07:29:09
User entered 'None (0)'	System	13 Sep 2020 07:29:09

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:51', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1'	System	13 Sep 2020 07:29:09
User entered 'None (0)'	System	13 Sep 2020 07:29:09

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:28:54', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1'	System	13 Sep 2020 07:29:09
User entered 'None (0)'	System	13 Sep 2020 07:29:09

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-13T02:29:02', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1'	System	13 Sep 2020 07:29:09
User entered 'No (N)'	System	13 Sep 2020 07:29:09

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-13T02:29:10', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'e58cd410-ca35-4434-9388-8c8d49f45aa1'	System	13 Sep 2020 07:29:09
User entered '13 Sep 2020 02:29'	System	13 Sep 2020 07:29:09

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 6'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:18:21
User entered 'Day 7'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:07', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36'	System	15 Sep 2020 14:56:42
User entered 'None (0)'	System	15 Sep 2020 14:56:42

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:15', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36'	System	15 Sep 2020 14:56:42
User entered 'None (0)'	System	15 Sep 2020 14:56:42

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36'	System	15 Sep 2020 14:56:42
User entered 'None (0)'	System	15 Sep 2020 14:56:42

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:20', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36'	System	15 Sep 2020 14:56:42
User entered 'None (0)'	System	15 Sep 2020 14:56:42

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36'	System	15 Sep 2020 14:56:42
User entered 'None (0)'	System	15 Sep 2020 14:56:42

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:25', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36'	System	15 Sep 2020 14:56:42
User entered 'None (0)'	System	15 Sep 2020 14:56:42

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

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 (e46a2e452722973a)', Time: '2020-09-15T09:56:29', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36'	System	15 Sep 2020 14:56:42
User entered 'No (N)'	System	15 Sep 2020 14:56:42

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-09-15T09:56:43', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '50df84d8-8a51-4063-8dd8-7d3fb24beb36'	System	15 Sep 2020 14:56:42
User entered '15 Sep 2020 09:56'	System	15 Sep 2020 14:56:42

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 21:18:21

US3252127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:50:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 21:18:21

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:19:52

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:19:52

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:19:52

US3252127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:19:52

US3252127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	16 Sep 2020 04:19:59

US3252127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 04:19:59

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	23 Sep 2020 03:15:29

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	23 Sep 2020 03:15:29

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	23 Sep 2020 03:15:29

US3252127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	23 Sep 2020 03:15:29

US3252127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	23 Sep 2020 03:15:34

US3252127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 03:15:34

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 05:05:35

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 05:05:35

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 05:05:35

US3252127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 05:05:35

US3252127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	30 Sep 2020 05:05:41

US3252127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 05:05:41

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:20:37

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:20:37

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:20:37

US3252127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:50:23

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	08 Oct 2020 06:20:37

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '15:29'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 15:29'	System	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '16'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '68'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:50:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 06:21:16

US3252127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:36

US3252127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:50:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:36

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:55

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 05:39:18
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'It is under unscheduled visit due to 0 quantity of kit type A. As per PPD GSS, we can use kit type UV for backup. US3252127 visit is recorded correctly in EDC.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 17:42:46
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:26:55
User entered '7 Oct 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:55

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:56'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:21:55

US3252127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 15:56'	System	08 Oct 2020 06:21:55

US3252127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:22:00

US3252127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 06:22:00

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 64'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[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 (e46a2e452722973a)', Time: '2020-10-14T18:56:32', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6863ad14-54a9-41b8-b905-469f8fbcfb72'	System	14 Oct 2020 23:57:13
User entered 'No (N)'	System	14 Oct 2020 23:57:13

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

Have you been exposed to someone with 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 (e46a2e452722973a)', Time: '2020-10-14T18:56:41', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6863ad14-54a9-41b8-b905-469f8fbcfb72'	System	14 Oct 2020 23:57:13
User entered 'No (N)'	System	14 Oct 2020 23:57:13

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-14T18:57:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '6863ad14-54a9-41b8-b905-469f8fbcb72'	System	14 Oct 2020 23:57:13
User entered '14 Oct 2020 18:57:12'	System	14 Oct 2020 23:57:13

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 71'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[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 (e46a2e452722973a)', Time: '2020-10-20T12:17:48', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1fc2e-4f95-44f2-b326-4464f6ece751'	System	20 Oct 2020 17:18:04
User entered 'No (N)'	System	20 Oct 2020 17:18:04

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

Have you been exposed to someone with 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 (e46a2e452722973a)', Time: '2020-10-20T12:17:54', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1fc2e-4f95-44f2-b326-4464f6ece751'	System	20 Oct 2020 17:18:04
User entered 'No (N)'	System	20 Oct 2020 17:18:04

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-20T12:18:01', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '97b1fc2e-4f95-44f2-b326-4464f6ece751'	System	20 Oct 2020 17:18:04
User entered '20 Oct 2020 12:18:01'	System	20 Oct 2020 17:18:04

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 78'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[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 (e46a2e452722973a)', Time: '2020-10-26T11:38:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8d4187fe-12fc-4088-9a83-a73beda94d1e'	System	26 Oct 2020 16:38:38
User entered 'No (N)'	System	26 Oct 2020 16:38:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

Have you been exposed to someone with 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 (e46a2e452722973a)', Time: '2020-10-26T11:38:27', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8d4187fe-12fc-4088-9a83-a73beda94d1e'	System	26 Oct 2020 16:38:38
User entered 'No (N)'	System	26 Oct 2020 16:38:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-10-26T11:38:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '8d4187fe-12fc-4088-9a83-a73beda94d1e'	System	26 Oct 2020 16:38:38
User entered '26 Oct 2020 11:38:35'	System	26 Oct 2020 16:38:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered 'Day 99'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[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 (e46a2e452722973a)', Time: '2020-11-15T15:49:12', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered 'Yes (Y)'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

Have you been exposed to someone with 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 (e46a2e452722973a)', Time: '2020-11-15T15:49:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered 'No (N)'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:49:35', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered 'Yes (Y)'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '1'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '1'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '1'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:33', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '0'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:37', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:52:06', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered 'Yes (Y)'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:51:56', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-15T15:52:24', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: 'd56cb6b6-e379-4305-90b2-4d7313fc5976'	System	15 Nov 2020 21:52:37
User entered '15 Nov 2020 15:52:24'	System	15 Nov 2020 21:52:37

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 23:07:38

US3252127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 23:07:38
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 23:07:38

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[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 (e46a2e452722973a)', Time: '2020-11-23T14:29:13', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c217d5c-aa23-47aa-9ad7-ec1385f77a82'	System	23 Nov 2020 20:29:23
User entered 'No (N)'	System	23 Nov 2020 20:29:23

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

Have you been exposed to someone with 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 (e46a2e452722973a)', Time: '2020-11-23T14:29:17', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c217d5c-aa23-47aa-9ad7-ec1385f77a82'	System	23 Nov 2020 20:29:23
User entered 'No (N)'	System	23 Nov 2020 20:29:23

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e46a2e452722973a)', Time: '2020-11-23T14:29:22', User OID: 'PatientReportedOutcome (US3252127)', ODM File OID: '7c217d5c-aa23-47aa-9ad7-ec1385f77a82'	System	23 Nov 2020 20:29:23
User entered '23 Nov 2020 14:29:22'	System	23 Nov 2020 20:29:23

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:23:06

US3252127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:50:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:23:06
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:23:06

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:39:00

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:39:00

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:39:00

US3252127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:50:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:39:00

US3252127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	04 Nov 2020 02:39:04

US3252127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:50:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 02:39:04

US3252127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:50:23

[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)	16 Oct 2020 20:54:06
User entered 'No (N)'	Joanna Gurrola (b) (4)	12 Aug 2020 19:51:23

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Temperature intolerance, LLT: Cold intolerance - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:42:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:42:55
Data point term sent to Coder	System	16 Oct 2020 20:56:58
User entered 'Cold Intolerance'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	27 Oct 2020 15:55:36
User entered empty; reason for change Data Entry Error	Uche Ehiemua (b) (4)	27 Oct 2020 15:55:36
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Oct 2020 20:56:57
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 20:56:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Oct 2020 20:56:44
User entered 'UN:UN' (non-conformant).	(b) (4), (b) (6)	16 Oct 2020 20:56:44
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Oct 2020 20:56:10
User entered '00:00'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:55:36
User entered '14 Sep 2020 00:00'	System	16 Oct 2020 20:56:57
User entered '14 Sep 2020 UN:UN' (non-conformant).	System	16 Oct 2020 20:56:44
User entered '14 Sep 2020 00:00'	System	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:50:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 20:56:10

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:31:58
User entered 'USA-US108-2020-mRNA-1273-P301000013'	System	04 Nov 2020 17:47:49
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 17:47:49

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:32:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 22:48:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 22:48:26
Data point term sent to Coder	System	03 Nov 2020 22:47:42
User entered 'Appendicitis'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:32:06
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:32:09
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:42:08
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:42:11
User entered '28 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:11:42
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:11:39
User entered '29 Oct 2020'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:11:49
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:29
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:36
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:37
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	21 Nov 2020 15:58:02
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		21 Nov 2020 15:58:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	21 Nov 2020 15:30:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:34
User entered '1'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Nov 2020 15:58:02
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4)	21 Nov 2020 15:30:50
User entered '28 Oct 2020'	Joanna Gurrola (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	21 Nov 2020 15:58:02
User entered empty; reason for change Data Entry Error	Joanna Gurrola (b) (4)	21 Nov 2020 15:30:50
User entered '29 Oct 2020'	Joanna Gurrola (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 22:17:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:17:17
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:20:25
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:20:26
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:20:27
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:20:49
User entered 'Not Related (NOT RELATED)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 20:26:52
Query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated.' (Site from Safety).	Joanna Gurrola (b) (4)	21 Nov 2020 15:47:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	21 Nov 2020 15:44:09
User opened query 'PV Query: As the last dose of study drug was given on 08 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:15:07
User entered 'None (NONE)'	Joanna Gurrola (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:43:02
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:43:03
User entered '1'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:43:05
User entered '1'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:43:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:43:11
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:15:42
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:15:27
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:15:18
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:14:55
User entered 'Patient presented with appendicitis on October 28th, got operated the same day and got discharged on October 29th.'	Joanna Gurrola (b) (4)	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 22:47:07

US3252127

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:50:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 22:47:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:50:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:51:57

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:20:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:20:11
Data point term sent to Coder	System	12 Aug 2020 19:55:56
User entered 'Fenofiberate'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypercholesteremia'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '134'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:19:32
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	12 Aug 2020 19:55:24
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:55:24

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:06:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:06:53
Data point term sent to Coder	System	28 Sep 2020 21:06:08
Coding entries removed.	(b) (4), (b) (6)	28 Sep 2020 21:05:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:59:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:59:24
Data point term sent to Coder	System	12 Aug 2020 19:57:59
User entered 'Montelukast'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:05:48
User entered 'Sinusitis'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:09:17
Query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' answered with 'indication was wrong. Corrected.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 21:06:11
User opened query 'Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 08:03:02
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:19:37
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	12 Aug 2020 19:57:20
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 19:57:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:04:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:04:48
Data point term sent to Coder	System	12 Aug 2020 20:02:15
User entered 'Pravaststin'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypercholesterol'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

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)	13 Aug 2020 11:19:41
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.'	Joanna Gurrola (b) (4)	12 Aug 2020 20:02:59
answered with 'Per source correct as is.' (Site from System).	(b) (4)	
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	12 Aug 2020 20:01:48
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4)	12 Aug 2020 20:01:48
	(b) (4)	

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:01:48

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DOXAZOSIN MESILATE, PRODUCTSYNONYM: DOXAZOSIN MESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:06:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:06:16
Data point term sent to Coder	System	12 Aug 2020 20:06:26
User entered 'Doxazosin mesylate'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:19:45
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	12 Aug 2020 20:05:30
User entered 'UN UNK 2018'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:05:30

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:08:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:08:11
Data point term sent to Coder	System	12 Aug 2020 20:07:29
User entered 'Metoprolol'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:19:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:07:07
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:07:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:10:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:10:12
Data point term sent to Coder	System	12 Aug 2020 20:09:34
User entered 'Amlodipine'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:19:54
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	12 Aug 2020 20:08:40
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:08:40

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:23:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:23:10
Data point term sent to Coder	System	12 Aug 2020 20:10:38
User entered 'Finisteride'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Enlarged Prostate'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'every other day (QOD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:19:58
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	12 Aug 2020 20:10:19
User entered 'UN UNK 2009'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:10:19

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:09:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:09:42
Data point term sent to Coder	System	28 Sep 2020 21:07:11
Coding entries removed.	(b) (4), (b) (6)	28 Sep 2020 21:06:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:00:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:00:19
Data point term sent to Coder	System	12 Aug 2020 20:14:52
User entered 'Diclofenac 1% topical gel'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Indication and please update to specify the location of Osteoarthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 22:42:57
Query 'Per DM CLR: Please review Indication and please update to specify the location of Osteoarthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.'	(b) (4), (b) (6)	28 Sep 2020 21:07:00
answered with 'HANDS' (Site from DM).		
User entered 'OSTEOARTHRITIS OF HANDS' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:06:55
User opened query 'Per DM CLR: Please review Indication and please update to specify the location of Osteoarthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Sep 2020 09:54:13
User entered 'Osteoarthritis'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review recorded Dose and Unit as these are not expected for this medication. Please verify if the number of Application would better represent the dose and unit or this topical medication. Please update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 22:43:00
Query 'Per DM CLR: Please review recorded Dose and Unit as these are not expected for this medication. Please verify if the number of Application would better represent the dose and unit or this topical medication. Please update applicable details as appropriate or provide clarification.'	(b) (4), (b) (6)	28 Sep 2020 21:22:28
answered with 'Medical History updated.' (Site from DM).		
User opened query 'Per DM CLR: Please review recorded Dose and Unit as these are not expected for this medication. Please verify if the number of Application would better represent the dose and unit or this topical medication. Please update applicable details as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Sep 2020 09:54:31
User entered '2'	Joanna Gurrola (b) (4)	12 Aug 2020 20:14:10
	(b) (4)	

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	28 Sep 2020 21:10:08
Data Entry Error		
User entered 'g (g)'	Joanna Gurrola (b) (4)	12 Aug 2020 20:14:10
	(b) (4)	

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'applications' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:10:08
User entered empty.	Joanna Gurrola (b) (4)	12 Aug 2020 20:14:10
	(b) (4)	

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:20:02
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	12 Aug 2020 20:14:10
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 20:14:10

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[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: OTHER DRUGS FOR CONSTIPATION, PRODUCT: LINACLOTIDE, PRODUCTSYNONYM: LINZESS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:20:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:20:09
Data point term sent to Coder	System	12 Aug 2020 20:19:04
User entered 'Linzess'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Constipation'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '72'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mcg'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query ' Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:19:34
Query ' Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'updated. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 21:24:18
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:24:11
User opened query ' Per DM CLR: Please review the start date of this medication as it was noted as prior to the start date of the corresponding MH record. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 06:40:50
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:20:06
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	12 Aug 2020 20:18:13
User entered 'UN UNK 2018'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:18:13

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:31:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:31:11
Data point term sent to Coder	System	12 Aug 2020 20:22:14
User entered 'Fluticasone Propionate'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)' reason for change:	Nancy Torrence (b) (4)	04 Nov 2020 13:47:39
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Joanna Gurrola (b) (4)	12 Aug 2020 20:21:43
	(b) (4)	

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:20:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:21:43
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 13:47:39
User entered '1'	System	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 13:47:39
User entered '1'	System	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 13:47:39
User entered '804 (804)'	System	12 Aug 2020 20:21:43

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:25:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:25:10
Data point term sent to Coder	System	12 Aug 2020 20:24:18
User entered 'Zolpidem'	Joanna Gurrola (b) (4)	12 Aug 2020 20:23:20
	(b) (4)	

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Insomnia'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:20:15
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	12 Aug 2020 20:23:20
User entered 'UN UNK 2010'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[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 SODIUM, PRODUCTSYNONYM: EUTHYROX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:27:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 20:27:10
Data point term sent to Coder	System	12 Aug 2020 20:26:23
User entered 'Euthyrox'	Joanna Gurrola (b) (4)	12 Aug 2020 20:25:25
	(b) (4)	

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypothyroid'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'mcg'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:20:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:25:25
User entered 'UN UNK 2019'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:25:25

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[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)	14 Aug 2020 07:17:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:17:21
Data point term sent to Coder	System	12 Aug 2020 20:28:29
User entered 'Multivitamins'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Dietary Supplement'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:20:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 20:27:46
User entered 'UN UNK 2009'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:27:46

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 13:48:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 13:48:19
Data point term sent to Coder	System	02 Nov 2020 20:30:39
Coding entries removed.	Joanna Gurrola (b) (4) (b) (4)	02 Nov 2020 20:30:26
Query 'Per MM: Please recode to B01AC' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 21:47:27
User opened query 'Per MM: Please recode to B01AC' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:45:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:53:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:53:49
Data point term sent to Coder	System	28 Sep 2020 21:27:02
Coding entries removed.	(b) (4), (b) (6)	28 Sep 2020 21:26:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 20:30:14

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	12 Aug 2020 20:30:14
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	12 Aug 2020 20:29:30
User entered 'Aspirin'	Joanna Gurrola (b) (4)	12 Aug 2020 20:29:28
	(b) (4)	

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	27 Oct 2020 15:47:38
User entered 'No (N)'	Joanna Gurrola (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'CAROTID ATHEROSCLEROSIS' reason for change: Data Entry Error	Joanna Gurrola (b) (4)	02 Nov 2020 20:30:26
User closed query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:15:15
User entered 'CAROTID ATHEROSCLEROSIS.' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:26:22
User entered 'Carotid Atherosclerosis .' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:26:04
User opened query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 08:01:42
User entered 'Heart'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Response noted however, please review and reconcile start date of CAROTID ATHEROSCLEROSIS on corresponding Med Hist eCRF as start date recorded as 'JUN-2020' and start date of meds 'UNK-2009' (difference of @11 years)?' answered with 'Med Hist eCRF has been reviewed and reconciled.' (Site from DM).	Joanna Gurrola (b) (4) (b) (4)	02 Nov 2020 20:32:51
User opened query 'Per CDM: Response noted however, please review and reconcile start date of CAROTID ATHEROSCLEROSIS on corresponding Med Hist eCRF as start date recorded as 'JUN-2020' and start date of meds 'UNK-2009' (difference of @11 years)?' (Site from DM).	(b) (4), (b) (6) (b) (4)	31 Oct 2020 10:39:06
User closed query 'Per DM CLR: Please review if start date is prior the start date of the associated medical condition. Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	31 Oct 2020 10:34:37
Query 'Per DM CLR: Please review if start date is prior the start date of the associated medical condition. Reconcile and update as appropriate.' answered with 'Start date is correct. Patient was placed 81mg aspirin prophylactically before for CAROTID ATHEROSCLEROSIS before having an episode.' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	27 Oct 2020 15:48:46
User opened query 'Per DM CLR: Please review if start date is prior the start date of the associated medical condition. Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	17 Oct 2020 06:22:27
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.' canceled (Site from System).	(b) (4), (b) (6) (b) (4)	13 Aug 2020 11:20:26
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	12 Aug 2020 20:29:28
User entered 'UN UNK 2009'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

v6.020 DTW (1102)

1973 of 2164

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:29:28

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: SITOSTEROL, PRODUCTSYNONYM: BETA-SITOSTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 22:35:48
Data point term sent to Coder	System	28 Sep 2020 21:04:01
Coding entries removed.	(b) (4), (b) (6)	28 Sep 2020 21:03:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: SITOSTEROL, PRODUCTSYNONYM: BETA SITOSTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:05:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:05:19
Data point term sent to Coder	System	12 Aug 2020 20:32:34
User entered 'Beta Sitosterol'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:16:18
Query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' answered with 'Medical history updated.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 21:03:53
User entered 'Benign prostatic hyperplasia' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 21:03:31
User opened query 'Per DM CLR: Please review Indication and please update to provide the medical condition rather than to record a body part. Please update indication and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 08:02:01
User entered 'Prostate'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 11:20:30
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	12 Aug 2020 20:31:38
User entered 'UN UNK 2009'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 20:31:38

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Medication was added with start date 07Sep2020. Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GASTRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 10:39:51
Query 'Per DM CLR: Medication was added with start date 07Sep2020. Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GASTRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'Condition is not worsening. Patient was unable to get medication refilled until recently.' (Site from DM).	Uche Ehiemua (b) (4)	27 Oct 2020 15:53:19
User opened query 'Per DM CLR: Medication was added with start date 07Sep2020. Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GASTRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:22:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 03:07:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 03:07:33
Data point term sent to Coder	System	09 Sep 2020 03:06:45
User entered 'omeprazole'	Shannon Moyer (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gastritis'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '7 Sep 2020'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	27 Oct 2020 15:53:54
User entered 'Yes (Y)'	Shannon Moyer (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Sep 2020' reason for change: Data Entry Error	Uche Ehiemua (b) (4)	27 Oct 2020 15:53:54
User entered empty.	Shannon Moyer (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shannon Moyer (b) (4) (b) (4)	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 03:05:55

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 22:08:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 22:08:45
Data point term sent to Coder	System	15 Sep 2020 22:08:08
User entered 'Tylenol'	(b) (4), (b) (6) (b) (4)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

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 timeframe. If the PAIN IN INJECTION SITE 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 of 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 PAIN IN INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 10:40:50
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN IN INJECTION SITE 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 of 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 PAIN IN INJECTION SITE did not meet the AE reporting criteria.' answered with 'As per protocol this is related to dosing. The solicited AR did not meet the AE criteria. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 21:00:56
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. Otherwise provide clarification' canceled (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 22:18:07

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN IN INJECTION SITE 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 of 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 PAIN IN INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 22:18:04
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. Otherwise provide clarification' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 19:26:27
User entered 'Pain in injection site'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '9 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 22:08:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 22:08:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 22:08:06
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 22:07:56
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this medication taken for solicited event?=No. However, there is a record of this event in diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 10:40:29
Query 'Per DM CLR: Was this medication taken for solicited event?=No. However, there is a record of this event in diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification. ' answered with 'Updated.' (Site from DM).	Uche Ehiemua (b) (4) (b) (4)	27 Oct 2020 15:54:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Uche Ehiemua (b) (4) (b) (4)	27 Oct 2020 15:54:22
User opened query 'Per DM CLR: Was this medication taken for solicited event?=No. However, there is a record of this event in diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 06:23:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 22:07:56

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:24:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:24:20
Data point term sent to Coder	System	08 Oct 2020 06:23:48
User entered 'Esomeprazole'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gastritis'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 06:23:20

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:47:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:47:26
Data point term sent to Coder	System	08 Oct 2020 06:24:49
User entered 'Sucralfate'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'Gastritis'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 06:24:32

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[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)	08 Oct 2020 06:29:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:29:23
Data point term sent to Coder	System	08 Oct 2020 06:28:49
User entered 'Influenza Vaccine'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'General Health'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'INJECTION'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Nancy Torrence (b) (4) (b) (4)	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 06:28:16

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:27:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:27:30
Data point term sent to Coder	System	04 Nov 2020 18:09:19
User entered 'Amoxicillin/clavulanate'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:20
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:23
User entered 'Appendicitis'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:26
User entered '500/125'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:29
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:35
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:42
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:45
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:47
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:49
User entered '29 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:44:51
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:58:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:58:26
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:45:03
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 10:50:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 18:08:42

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:50:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Query 'Concomitant procedures are noted, please review and reconcile. ' answered with 'updated.' (Site from CRA).	Joanna Gurrola (b) (4) (b) (4)	21 Nov 2020 16:04:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Joanna Gurrola (b) (4) (b) (4)	21 Nov 2020 16:04:24
User opened query 'Concomitant procedures are noted, please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 21:46:10
User entered 'No (N)' reason for change: Data Entry Error	Shannon Moyer (b) (4) (b) (4)	20 Aug 2020 19:26:01
User entered 'Yes (Y)'	Joanna Gurrola (b) (4) (b) (4)	12 Aug 2020 20:37:51

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:50:23

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:56:43
User entered '28 Oct 2020'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 16:00:07

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:50:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:56:44
User entered 'Appendectomy'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 16:00:07

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:50:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:56:46
User entered 'Adverse Event (AE)'	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 16:00:07

US3252127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:50:23

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:56:47
User entered empty.	Shannon Moyer (b) (4) (b) (4)	09 Nov 2020 16:00:07

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'USA-US108-2020-MRNA-1273-P301000013'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Yes (Y)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Yes (Y)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Joel'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Solis'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered '5201 N. 10th Street'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Mcallen'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'TX'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'carmpa'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:27:06
User entered 'US'	System	04 Nov 2020 17:48:34

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 20:27:18
User entered '1'	System	04 Nov 2020 17:48:34

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'USA-US108-2020-MRNA-1273-P301000013'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Yes (Y)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Yes (Y)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Joel'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Solis'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered '5201 N. 10th Street'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Mcallen'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'TX'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'carmpa'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:27:06
User entered 'US'	System	04 Nov 2020 17:48:34

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 20:27:18
User entered '1'	System	04 Nov 2020 17:48:34

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:50:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '04/Nov/2020 12:48'	System	04 Nov 2020 17:48:34

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:50:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:27:06
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 17:48:34

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'USA-US108-2020-MRNA-1273-P301000013'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Yes (Y)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Yes (Y)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'No (N)'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Joel'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Solis'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered '5201 N. 10th Street'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'Mcallen'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'TX'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 17:48:19
User entered 'carmpa'	System	04 Nov 2020 17:47:49

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:27:06
User entered 'US'	System	04 Nov 2020 17:48:34

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 26 Nov 2020 10:50:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 20:27:18
User entered '1'	System	04 Nov 2020 17:48:34

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:50:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Nov/2020 15:27'	System	23 Nov 2020 20:27:18

US3252127

Folder: SAE USA-US108-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:50:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 20:27:18