

US3312629 (Prod: Johnson County Clin-Trials)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:56:40

All time stamps listed in this document are displayed in GMT

US3312629

Form: Participant Creation

Generated On: 26 Nov 2020 10:56:40

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:56:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:56:40

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

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)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

Condition	CURRENT HIATAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

Condition	OBESITY
Start date (dd MMM yyyy)	UN JAN 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	UN JUN 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

Condition	PARTIAL COLECTOMY
Start date (dd MMM yyyy)	UN JUN 2015
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 JUN 2015
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JUN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

Condition	CODEINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:06 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:06
Height (<i>xxx.x</i>)	65.0 in
Weight (<i>xxx.x</i>)	219.4 lb
BMI (<i>xxx.x</i>)	36.58641 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input checked="" 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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

Date of assessment (<i>dd MMM yyyy</i>)	11 SEP 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2018
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	RESIDES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

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

What was the participant's randomization number? 113445

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:40

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:06
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:57
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020
What was the treatment time? (00:00-23:59)	13:26 (24 HR)
Treatment Date and Time (derived)	11 SEP 2020 13:26
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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:35 (24 HR)
Collection date and time (derived)	11 SEP 2020 12:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:40

Collection date (<i>dd MMM yyyy</i>)			11 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	12:35	11 SEP 2020 12:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 13:59

PC Open Date & Time

11 SEP 2020 13:46

PC Close Date & Time

11 SEP 2020 16:16

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 97.7 °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	11 SEP 2020 18:01
PC Open Date & Time	11 SEP 2020 17:11
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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 SEP 2020 18:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:49

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

14 SEP 2020 18:45

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 18:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020 19:51

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

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

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

17 SEP 2020 19:36

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020 13:59

PC Open Date & Time

11 SEP 2020 13:46

PC Close Date & Time

11 SEP 2020 16:16

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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

11 SEP 2020 18:02

PC Open Date & Time

11 SEP 2020 17:11

PC Close Date & Time

12 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 18:28

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020 19:47

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020 18:44

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020 18:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020 19:51

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 SEP 2020 19:35

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 14:00
PC Open Date & Time	11 SEP 2020 13:46
PC Close Date & Time	11 SEP 2020 16:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 18:02
PC Open Date & Time	11 SEP 2020 17:11
PC Close Date & Time	12 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:29
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:47
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:44
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 18:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 19:50
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:35
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

Was Contact Attempted?

Yes ☒

No ☐

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

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

Was Contact Attempted?

Yes ☒

No ☐

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

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

Was Contact Attempted?

Yes ☒

No ☐

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

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 10:25
Temperature (xxx.x)	98.5 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)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

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)	13 OCT 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:45
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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)	13 OCT 2020
What was the treatment time? (00:00-23:59)	11:14 (24 HR)
Treatment Date and Time (derived)	13 OCT 2020 11:14
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

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	10:46 (24 HR)
Collection date and time (derived)	13 OCT 2020 10:46

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:40

Collection date (<i>dd MMM yyyy</i>)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:33	13 OCT 2020 10:33
Nasopharyngeal Swab 2	No		

US3312629

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

13 OCT 2020 11:47

PC Open Date & Time

13 OCT 2020 11:34

PC Close Date & Time

13 OCT 2020 14:04

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 97.9 °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	13 OCT 2020 19:39
PC Open Date & Time	13 OCT 2020 14:59
PC Close Date & Time	14 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 19:42

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

15 OCT 2020 19:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

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

97.4 °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

16 OCT 2020 20:20

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 19:41

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 19:46

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 20:56

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

13 OCT 2020 11:48

PC Open Date & Time

13 OCT 2020 11:34

PC Close Date & Time

13 OCT 2020 14:04

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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

13 OCT 2020 19:37

PC Open Date & Time

13 OCT 2020 14:59

PC Close Date & Time

14 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

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

14 OCT 2020 19:40

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

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

15 OCT 2020 19:15

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

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

16 OCT 2020 20:19

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

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

17 OCT 2020 19:39

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

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

18 OCT 2020 19:46

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

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

19 OCT 2020 20:56

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 11:49
PC Open Date & Time	13 OCT 2020 11:34
PC Close Date & Time	13 OCT 2020 14:04

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 19:36
PC Open Date & Time	13 OCT 2020 14:59
PC Close Date & Time	14 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 19:39
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 19:14
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 20:18
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 19:38
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:45
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 ☒

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 20:56
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 20 OCT 2020 13:45

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 13:44
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

Was Contact Attempted?

Yes ☒

No ☐

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

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

Was Contact Attempted?

Yes ☒

No ☐

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

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

Was Contact Attempted?

Yes ☒

No ☐

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

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:45 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 10:45
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312629

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	16 NOV 2020
Collection time (<i>00:00-23:59</i>)	11:29 (24 HR)
Collection date and time (derived)	16 NOV 2020 11:29

US3312629

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 04:28:25
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

18 NOV 2020 04:53:08

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
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	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 NOV 2020 14:53:12
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

03 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

28 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

Patient Cloud Open Date & Time	03 OCT 2021 00:01
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Patient Cloud Close Date & Time	07 OCT 2021 23:59
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US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2022 00:01
Patient Cloud Close Date & Time	21 APR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3312629

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:40

Date of Contact	23 NOV 2020
Time of Contact	09:53
Date and Time of Contact (derived)	23 NOV 2020 09:53
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	344 of 2188	

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	348 of 2188	

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	352 of 2188	

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:56:40

Date of Visit

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Yes ☐

No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Yes ☐

No ☐

Date of Test

Type of Test Performed

Nasopharyngeal Swab ☐

Nasal Swab ☐

Saliva Test ☐

Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study
Central Lab?

Yes ☐

No ☐

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified?

Yes ☐

No ☐

COVID-19 Positive (CSA Programming Field Only)

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:56:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:56:40

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	11:33 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 11:33
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	217.8 lb
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3312629

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:56:40

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

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.

US3312629

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:56:40

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3312629

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:56:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

AEID	USA-US300-2020-MRNA-1273-P30 1000012
Adverse event	SMALL BOWEL OBSTRUCTION
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)	06 NOV 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)	10 NOV 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)	06 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	10 NOV 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)	367 of 2188

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

PER PHONE CALL WITH
SUBJECT 11/09/2020
53 Y/O WOMAN WITH H/O
DIVERTICULOSIS AND PARTIAL
COLECTOMY, SLEEVE
GASTRECTOMY, INCISIONAL
HERNIAS, & HIATAL HERNIA
WHO DEVELOPED ABDOMINAL
PAIN ON 06NOV2020 THAT
RESULTED IN ER VISIT. SMALL
BOWEL OBSTRUCTION WAS
DIAGNOSED; EVAL INCLUDED
CT SCAN AND XRAYs.TREATED
WITH IV FENTANYL AND
TORADOL AND NPO WITHOUT
NG TUBE,HER DIET WAS
ADVANCED TO CLEAR LIQUIDS
BY 08NOV2020. HER CARE
TEAM HOPES TO ADVANCE TO
FULL LIQUIDS TODAY,
09NOV2020. SUBJECT'S PAIN
WAS WELL CONTROLLED AND
SHE WAS IN NO DISTRESS AT
TIME OF PHONE CONTACT
TODAY. SBO BELIEVED TO BE
RELATED TO ADHESIONS
RELATED TO PREVIOUS
PROCEDURES. THIS IS AN SAE
OF SBO, NR TO IP. UPDATE
11NOV2020: SUBJECT
DISCHARGED FROM HOSPITAL
WITHOUT ADDITIONAL
INTERVENTION, HAS HAD
BOWEL MOVEMENTS AND
WITHOUT PAIN. MR
PENDING.UPDATE:MEDICAL
RECORDS REVIEWED.SUBJECT

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

WAS ADMITTED 06NOV2020
WITH PARTIAL SMALL BOWEL
OBSTRUCTION RELATED TO
ADHESIONS FROM HISTORY OF
MULTIPLE ABDOMINAL
SURGERIES.ON DATE OF
ADMISSION DEVELOPED
EPIGASTRIC ABDOMINAL PAIN
AT APPROXIMATELY 12:45 PM
THAT PROGRESSIVELY
WORSENER TO 8 OUT OF 10
SEVERITY OVER HOURS.SELF
INDUCED EMESIS
(NON-BLOODY) DID NOT
RELIEVE PAIN.SHE WENT TO
LOCAL ER WHERE CARE WAS
INITIATED BUT TRANSFERRED
TO ANOTHER SAME
DAY.OVERALL WORK-UP
REVEALED NEGATIVE COVID
TEST 06NOV2020,DILATED
LOOPS OF BOWEL WITHOUT
EVIDENCE OF PNEUMATOSIS
OR ISCHEMIA AND
CONSISTENT WITH PARTIAL
SMALL BOWEL OBSTRUCTION
ON IMAGING, NEUTROPHIL
ELEVATION TO 9000/MICROL
WITHOUT SIGNS OF INFECTION
CONSISTENT WITH STRESS
AND PAIN RELATED
ELEVATION, ABDOMINAL PAIN
THAT RESOLVED WITH IV PAIN
MEDS, AND LACTATE LEVEL
OF 3.14 THAT DECREASED TO
1.3 WITH IV
FLUIDS.TREATMENT WAS

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

CONSERVATIVE WITH NPO,
THEN ADVANCEMENT OF
DIET.ON DAY OF DC 10NOV2020
SUBJECT LOOKED AND FELT
WELL, HAD 2 NORMAL BOWEL
MOVEMENTS, AND A MILD
HYPOKALEMIA OF 3.3 THAT
WAS CORRECTED.AE
RESOLVED

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

AEID	
Adverse event	LEFT TENNIS ELBOW (LATERAL EPICONDYLITIS)
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)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	372 of 2188

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:56:40

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

Yes ☒

No ☐

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCHOLESTEROLEMIA
Dose per administration	80
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

	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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	ESCITALOPRAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CURRENT HIATAL HERNIA
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 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

	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 2016	
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	MONTELUKAST
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
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 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 checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	NIGHTLY 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

	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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	AMITRIPYLINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MIGRAINES
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 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 checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	NIGHTLY 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	FAMOTIDINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ACID REFLUX
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 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

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 2016
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	LORATIDINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

	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 2018
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	FLUTICASONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
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	SPRAY
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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	ASPIRIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	GENERAL HEALTH MAINTENANCE
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

	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"/>
<hr/>		
If route of administration is Other, specify <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) <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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	SUMATRIPTAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MIGRAINES
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

	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 FEB 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)		<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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	MIGRAINES
Dose per administration	800
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

	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 2000
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MIGRAINES
Dose per administration	1000
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 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 checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	LIRAGLUTIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OBESITY
Dose per administration	3
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" 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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JUN 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	TORADOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	60
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		06 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		08 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		06 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		08 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	SEASONAL INFLUENZA VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SEASONAL INFLUENZA PROPHYLAXIS
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	CORTISONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LEFT TENNIS ELBOW
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 type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	INTRAARTICULAR	
Start date (dd MMM yyyy)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 NOV 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LEFT TENNIS ELBOW
Dose per administration	800
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 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 checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 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"/>

US3312629

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:56:40

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3312629

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:56:40

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

US3312629

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:56:40

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 ☐

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

SAEID	USA-US300-2020-MRNA-1273-P301000012
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:40

SAEID	USA-US300-2020-MRNA-1273-P301000012
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/NOV/2020 22:11
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

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:40

SAEID	USA-US300-2020-MRNA-1273-P301000012
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/NOV/2020 13:36
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

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:56:40

SAEID	USA-US300-2020-MRNA-1273-P301000012
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:58
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

US3312629 (Prod: Johnson County Clin-Trials)

US3312629

Form: Participant Creation

Generated On: 26 Nov 2020 10:56:40

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3312629'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Sep 2020 16:29:22

US3312629

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 20:53:45
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' answered with 'updayed' (Site from DM).	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:21
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:41:32
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:28:54

US3312629

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Sep 2020 16:29:24

US3312629

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:28:54

US3312629

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Sep 2020 18:28:54

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 16:29:25

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Age](#)

Audit	User	Time (GMT)
User entered '53'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '53'	System	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

White

Audit	User	Time (GMT)
User entered 'I'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:40

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Sep 2020 16:29:24

US3312629

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:56:40

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:56:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:31

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Oct 2020 16:26:18
Data point term sent to Coder	System	05 Oct 2020 16:25:35
User entered 'post menopausal'	Karol Moore (b) (4)	05 Oct 2020 16:24:45
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2018'	System	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

[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)	05 Oct 2020 16:26:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:17
Data point term sent to Coder	System	05 Oct 2020 16:25:36
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	05 Oct 2020 16:24:56
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Oct 2020 16:26:18
Data point term sent to Coder	System	05 Oct 2020 16:25:35
User entered 'anxiety'	Karol Moore (b) (4)	05 Oct 2020 16:25:06
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2018'	System	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:05:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:05:22
Data point term sent to Coder	System	05 Oct 2020 16:25:37
User entered 'current hiatal hernia'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2016'	System	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:27:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:27:18
Data point term sent to Coder	System	05 Oct 2020 16:26:39
User entered 'seasonal allergies'	Karol Moore (b) (4)	05 Oct 2020 16:25:40
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2018'	System	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:27:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:27:19
Data point term sent to Coder	System	05 Oct 2020 16:26:38
User entered 'migraines'	Karol Moore (b) (4)	05 Oct 2020 16:25:50
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2000'	System	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:43:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:43:23
Data point term sent to Coder	System	05 Oct 2020 16:42:15
User entered 'obesity'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un Jan 2017'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '01 Jun 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2017'	System	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jun 2020'	System	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2020'	System	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

[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: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:43:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:43:23
Data point term sent to Coder	System	05 Oct 2020 16:42:18
User entered 'acid reflux'	Karol Moore (b) (4)	05 Oct 2020 16:41:55
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2016'	System	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:44:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:44:27
Data point term sent to Coder	System	05 Oct 2020 16:43:21
User entered 'laparoscopic sleeve gastrectomy'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un Jan 2017'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un Jan 2017'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2017'	System	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2017'	System	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLG: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:45:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:45:24
Data point term sent to Coder	System	05 Oct 2020 16:44:24
User entered 'diverticulosis'	Karol Moore (b) (4)	05 Oct 2020 16:43:48
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un Jun 2005'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jun 2005'	System	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2005'	System	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2015'	System	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colectomy, LLT: Colectomy partial - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:45:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:45:25
Data point term sent to Coder	System	05 Oct 2020 16:44:24
User entered 'partial colectomy'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un Jun 2015'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	05 Oct 2020 16:45:37
User entered 'UN Jun 2015' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:45:37
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	05 Oct 2020 16:44:03
User entered 'un UNK 2015'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jun 2015'	System	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2015'	System	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jun 2015'	System	05 Oct 2020 16:45:37
User entered 'Jan 2015'	System	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2015'	System	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:33
Data point term sent to Coder	System	05 Oct 2020 16:50:38
User entered 'tramadol allergy'	Karol Moore (b) (4)	05 Oct 2020 16:50:11
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2008'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2008'	System	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:32
Data point term sent to Coder	System	05 Oct 2020 16:50:38
User entered 'codeine allergy'	Karol Moore (b) (4)	05 Oct 2020 16:50:23
	(b) (4)	

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '1995'	System	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:01:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:01:03
Data point term sent to Coder	System	19 Nov 2020 21:00:25
User entered 'inguinal hernia'	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	(b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	(b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2017'	System	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '2017'	System	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '12:06'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:06'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '65.0' in	Karol Moore (b) (4)	05 Oct 2020 16:51:46
DataPoint set to visible.	(b) (4) System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '219.4' lb	Karol Moore (b) (4)	05 Oct 2020 16:51:46
DataPoint set to visible.	(b) (4) System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '36.58641'	System	05 Oct 2020 16:51:46
DataPoint set to visible.	System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	05 Oct 2020 16:51:46
DataPoint set to visible.	System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:52:16

US3312629

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:52:16

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:56:40

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:40

[Specify](#)

Audit	User	Time (GMT)
User entered 'resides in community with ongoing person to person transmission'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:58

US3312629

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:58

US3312629

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:58

US3312629

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Sep 2020 18:29:58

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Sep 2020 17:59:28

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '113445'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Sep 2020 17:59:28

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	11 Sep 2020 17:59:28

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 16:56:30
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:11:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:11:51

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:40

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:40

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:40

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:40

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '12:06'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:06'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Pulse (xxx)

Audit	User	Time (GMT)
User entered '72'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '14'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '64'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:40

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:40

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '13:57'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:57'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Pulse (xxx)

Audit	User	Time (GMT)
User entered '79'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:59:11

US3312629

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:59:11

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '13:26'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:26'	System	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:29

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:29

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:35'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:29

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:35'	System	05 Oct 2020 17:02:29

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:35'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:35'	System	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:46

US3312629

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Oct 2020 17:02:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:14', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0fa2a249-2358-4e3b-95d9-649bd5627b32'	System	11 Sep 2020 18:59:32
User entered 'Yes (Y)'	System	11 Sep 2020 18:59:32

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0fa2a249-2358-4e3b-95d9-649bd5627b32'	System	11 Sep 2020 18:59:32
User entered '98.2'	System	11 Sep 2020 18:59:32

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0fa2a249-2358-4e3b-95d9-649bd5627b32'	System	11 Sep 2020 18:59:32
User entered 'No (N)'	System	11 Sep 2020 18:59:32

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0fa2a249-2358-4e3b-95d9-649bd5627b32'	System	11 Sep 2020 18:59:32
User entered '11 Sep 2020 13:59'	System	11 Sep 2020 18:59:32

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:46'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:16'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:17', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ab3d3e36-cde4-428f-86ac-80d22e2d7a0c'	System	11 Sep 2020 23:01:40
User entered 'Yes (Y)'	System	11 Sep 2020 23:01:40

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ab3d3e36-cde4-428f-86ac-80d22e2d7a0c'	System	11 Sep 2020 23:01:40
User entered '97.7'	System	11 Sep 2020 23:01:40

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ab3d3e36-cde4-428f-86ac-80d22e2d7a0c'	System	11 Sep 2020 23:01:40
User entered 'No (N)'	System	11 Sep 2020 23:01:40

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ab3d3e36-cde4-428f-86ac-80d22e2d7a0c' User entered '11 Sep 2020 18:01'	System	11 Sep 2020 23:01:40
	System	11 Sep 2020 23:01:40

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:11'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 2'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '78744b89-16e7-48d1-b2b3-06121cbe04b3'	System	12 Sep 2020 23:30:09
User entered 'Yes (Y)'	System	12 Sep 2020 23:30:09

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '78744b89-16e7-48d1-b2b3-06121cbe04b3'	System	12 Sep 2020 23:30:09
User entered '98.3'	System	12 Sep 2020 23:30:09

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:30:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '78744b89-16e7-48d1-b2b3-06121cbe04b3'	System	12 Sep 2020 23:30:09
User entered 'No (N)'	System	12 Sep 2020 23:30:09

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:30:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '78744b89-16e7-48d1-b2b3-06121cbe04b3'	System	12 Sep 2020 23:30:09
User entered '12 Sep 2020 18:30'	System	12 Sep 2020 23:30:09

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 3'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:49:16', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a7b3d521-450b-414d-9255-496264546a9a'	System	14 Sep 2020 00:49:37
User entered 'Yes (Y)'	System	14 Sep 2020 00:49:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:49:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a7b3d521-450b-414d-9255-496264546a9a'	System	14 Sep 2020 00:49:37
User entered '97.8'	System	14 Sep 2020 00:49:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:49:32', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a7b3d521-450b-414d-9255-496264546a9a'	System	14 Sep 2020 00:49:37
User entered 'No (N)'	System	14 Sep 2020 00:49:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:49:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a7b3d521-450b-414d-9255-496264546a9a'	System	14 Sep 2020 00:49:37
User entered '13 Sep 2020 19:49'	System	14 Sep 2020 00:49:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 4'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:54', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '674f0226-e7d5-4dcf-b370-a223f08a75dc' User entered 'Yes (Y)'	System	14 Sep 2020 23:45:10

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '674f0226-e7d5-4dcf-b370-a223f08a75dc' User entered '98.3'	System	14 Sep 2020 23:45:10

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:45:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '674f0226-e7d5-4dcf-b370-a223f08a75dc'	System	14 Sep 2020 23:45:10
User entered 'No (N)'	System	14 Sep 2020 23:45:10

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:45:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '674f0226-e7d5-4dcf-b370-a223f08a75dc'	System	14 Sep 2020 23:45:10
User entered '14 Sep 2020 18:45'	System	14 Sep 2020 23:45:10

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 5'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '74bc4a19-0e85-4a5b-aa66-d703e32e6370'	System	15 Sep 2020 23:02:37
User entered 'Yes (Y)'	System	15 Sep 2020 23:02:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '74bc4a19-0e85-4a5b-aa66-d703e32e6370'	System	15 Sep 2020 23:02:37
User entered '97.8'	System	15 Sep 2020 23:02:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '74bc4a19-0e85-4a5b-aa66-d703e32e6370'	System	15 Sep 2020 23:02:37
User entered 'No (N)'	System	15 Sep 2020 23:02:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:30', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '74bc4a19-0e85-4a5b-aa66-d703e32e6370'	System	15 Sep 2020 23:02:37
User entered '15 Sep 2020 18:02'	System	15 Sep 2020 23:02:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 6'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b43d5d62-94c5-4b28-ac1b-138af060230e'	System	17 Sep 2020 00:51:59
User entered 'Yes (Y)'	System	17 Sep 2020 00:51:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b43d5d62-94c5-4b28-ac1b-138af060230e' User entered '97.6'	System	17 Sep 2020 00:51:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:54', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b43d5d62-94c5-4b28-ac1b-138af060230e'	System	17 Sep 2020 00:51:59
User entered 'No (N)'	System	17 Sep 2020 00:51:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b43d5d62-94c5-4b28-ac1b-138af060230e'	System	17 Sep 2020 00:51:59
User entered '16 Sep 2020 19:51'	System	17 Sep 2020 00:51:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 7'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1c856f67-e03c-408b-b60b-d36113e9fb32'	System	18 Sep 2020 00:36:39
User entered 'Yes (Y)'	System	18 Sep 2020 00:36:39

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:36:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1c856f67-e03c-408b-b60b-d36113e9fb32'	System	18 Sep 2020 00:36:39
User entered '98.1'	System	18 Sep 2020 00:36:39

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:36:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1c856f67-e03c-408b-b60b-d36113e9fb32'	System	18 Sep 2020 00:36:39
User entered 'No (N)'	System	18 Sep 2020 00:36:39

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:36:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1c856f67-e03c-408b-b60b-d36113e9fb32'	System	18 Sep 2020 00:36:39
User entered '17 Sep 2020 19:36'	System	18 Sep 2020 00:36:39

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db'	System	11 Sep 2020 19:00:06
User entered 'None (1)'	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db'	System	11 Sep 2020 19:00:06
User entered 'No (N)'	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db'	System	11 Sep 2020 19:00:06
User entered 'No (N)'	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db'	System	11 Sep 2020 19:00:06
User entered 'None (1)'	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db'	System	11 Sep 2020 19:00:06
User entered '11 Sep 2020 13:59'	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:46'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:16'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered 'None (1)'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered 'No (N)'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered 'No (N)'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered 'None (1)'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:16', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered '11 Sep 2020 18:02'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:11'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 2'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered 'None (1)'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered 'No (N)'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered 'No (N)'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered 'None (1)'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered '12 Sep 2020 18:28'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 3'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:46:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c'	System	14 Sep 2020 00:47:09
User entered 'None (1)'	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:46:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c'	System	14 Sep 2020 00:47:09
User entered 'No (N)'	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:46:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c'	System	14 Sep 2020 00:47:09
User entered 'No (N)'	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:03', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c' User entered 'None (1)'	System	14 Sep 2020 00:47:09
	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:05', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c'	System	14 Sep 2020 00:47:09
User entered '13 Sep 2020 19:47'	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 4'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:43:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered 'None (1)'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:43:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered 'No (N)'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered 'No (N)'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered 'None (1)'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:18', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered '14 Sep 2020 18:44'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 5'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered 'None (1)'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered 'No (N)'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:31', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered 'No (N)'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered 'None (1)'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered '15 Sep 2020 18:01'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 6'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049'	System	17 Sep 2020 00:51:32
User entered 'None (1)'	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049'	System	17 Sep 2020 00:51:32
User entered 'No (N)'	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049'	System	17 Sep 2020 00:51:32
User entered 'No (N)'	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049'	System	17 Sep 2020 00:51:32
User entered 'None (1)'	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049'	System	17 Sep 2020 00:51:32
User entered '16 Sep 2020 19:51'	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 7'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269'	System	18 Sep 2020 00:35:42
User entered 'None (1)'	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269'	System	18 Sep 2020 00:35:42
User entered 'No (N)'	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269'	System	18 Sep 2020 00:35:42
User entered 'No (N)'	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269'	System	18 Sep 2020 00:35:42
User entered 'None (1)'	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:38', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269'	System	18 Sep 2020 00:35:42
User entered '17 Sep 2020 19:35'	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'None (0)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:08', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'None (0)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:11', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'None (0)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'None (0)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'None (0)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:17', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'None (0)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:20', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'No (N)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:23', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered '11 Sep 2020 14:00'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 13:46'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:16'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928'	System	11 Sep 2020 23:03:16
User entered 'None (0)'	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:26', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928'	System	11 Sep 2020 23:03:16
User entered 'None (0)'	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928'	System	11 Sep 2020 23:03:16
User entered 'None (0)'	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928'	System	11 Sep 2020 23:03:16
User entered 'None (0)'	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:35', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928'	System	11 Sep 2020 23:03:16
User entered 'None (0)'	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928'	System	11 Sep 2020 23:03:16
User entered 'None (0)'	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928'	System	11 Sep 2020 23:03:16
User entered 'No (N)'	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928' User entered '11 Sep 2020 18:02'	System	11 Sep 2020 23:03:16
	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:11'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 2'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7'	System	12 Sep 2020 23:29:30
User entered 'None (0)'	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7'	System	12 Sep 2020 23:29:30
User entered 'None (0)'	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:09', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7'	System	12 Sep 2020 23:29:30
User entered 'None (0)'	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7'	System	12 Sep 2020 23:29:30
User entered 'None (0)'	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:18', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7'	System	12 Sep 2020 23:29:30
User entered 'None (0)'	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:20', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7'	System	12 Sep 2020 23:29:30
User entered 'None (0)'	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7'	System	12 Sep 2020 23:29:30
User entered 'No (N)'	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7'	System	12 Sep 2020 23:29:30
User entered '12 Sep 2020 18:29'	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 3'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f'	System	14 Sep 2020 00:47:46
User entered 'None (0)'	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f'	System	14 Sep 2020 00:47:46
User entered 'None (0)'	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:21', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f'	System	14 Sep 2020 00:47:46
User entered 'None (0)'	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:26', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f'	System	14 Sep 2020 00:47:46
User entered 'None (0)'	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f'	System	14 Sep 2020 00:47:46
User entered 'None (0)'	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f'	System	14 Sep 2020 00:47:46
User entered 'None (0)'	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f'	System	14 Sep 2020 00:47:46
User entered 'No (N)'	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:42', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f'	System	14 Sep 2020 00:47:46
User entered '13 Sep 2020 19:47'	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 4'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1'	System	14 Sep 2020 23:44:52
User entered 'None (0)'	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1'	System	14 Sep 2020 23:44:52
User entered 'None (0)'	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1'	System	14 Sep 2020 23:44:52
User entered 'None (0)'	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1'	System	14 Sep 2020 23:44:52
User entered 'None (0)'	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1'	System	14 Sep 2020 23:44:52
User entered 'None (0)'	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:44', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1'	System	14 Sep 2020 23:44:52
User entered 'None (0)'	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1'	System	14 Sep 2020 23:44:52
User entered 'No (N)'	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered '14 Sep 2020 18:44'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 5'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'None (0)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'None (0)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'None (0)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'None (0)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'None (0)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'None (0)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'No (N)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered '15 Sep 2020 18:02'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 6'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:31', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'No (N)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered '16 Sep 2020 19:50'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 7'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:34:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:03', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:16', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'No (N)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:18', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered '17 Sep 2020 19:35'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:03:09

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:03:09

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:03:09

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:03:09

US3312629

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:03:24

US3312629

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Oct 2020 17:03:24

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:07

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:07

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:07

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:07

US3312629

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:10

US3312629

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Oct 2020 17:04:10

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:29

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:29

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:29

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:29

US3312629

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:32

US3312629

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Oct 2020 17:04:32

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:25:39

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 16:25:39

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 16:25:39

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	13 Oct 2020 16:25:39

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '10:25'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:25'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11:45'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:45'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:46

US3312629

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:46

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11:14'	(b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:14'	System	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:01

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:01

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:46'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:01

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:46'	System	15 Oct 2020 16:25:01

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:33'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 10:33'	System	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 16:26:05

US3312629

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:26:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac0913bd-8645-4a74-bf8b-8d55106a9086' User entered 'Yes (Y)'	System	13 Oct 2020 16:47:44
	System	13 Oct 2020 16:47:44

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac0913bd-8645-4a74-bf8b-8d55106a9086' User entered '98.1'	System	13 Oct 2020 16:47:44
	System	13 Oct 2020 16:47:44

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac0913bd-8645-4a74-bf8b-8d55106a9086'	System	13 Oct 2020 16:47:44
User entered 'No (N)'	System	13 Oct 2020 16:47:44

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac0913bd-8645-4a74-bf8b-8d55106a9086' User entered '13 Oct 2020 11:47'	System	13 Oct 2020 16:47:44
	System	13 Oct 2020 16:47:44

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:34'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:04'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:37:38', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '3382d5c8-403a-410a-81fd-29a87df8ec8c'	System	14 Oct 2020 00:39:52
User entered 'Yes (Y)'	System	14 Oct 2020 00:39:52

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:39:44', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '3382d5c8-403a-410a-81fd-29a87df8ec8c'	System	14 Oct 2020 00:39:52
User entered '97.9'	System	14 Oct 2020 00:39:52

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:39:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '3382d5c8-403a-410a-81fd-29a87df8ec8c'	System	14 Oct 2020 00:39:52
User entered 'No (N)'	System	14 Oct 2020 00:39:52

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:39:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '3382d5c8-403a-410a-81fd-29a87df8ec8c' User entered '13 Oct 2020 19:39'	System	14 Oct 2020 00:39:52
	System	14 Oct 2020 00:39:52

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 2'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:41:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'db187be3-f717-4069-ae56-49c1c5cef249'	System	15 Oct 2020 00:42:30
User entered 'Yes (Y)'	System	15 Oct 2020 00:42:30

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:42:20', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'db187be3-f717-4069-ae56-49c1c5cef249'	System	15 Oct 2020 00:42:30
User entered '96.8'	System	15 Oct 2020 00:42:30

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:42:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'db187be3-f717-4069-ae56-49c1c5cef249'	System	15 Oct 2020 00:42:30
User entered 'No (N)'	System	15 Oct 2020 00:42:30

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:42:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'db187be3-f717-4069-ae56-49c1c5cef249'	System	15 Oct 2020 00:42:30
User entered '14 Oct 2020 19:42'	System	15 Oct 2020 00:42:30

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 3'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2b876256-52e9-46c4-a551-acd3e827e00b' User entered 'Yes (Y)'	System	16 Oct 2020 00:16:05
	System	16 Oct 2020 00:16:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2b876256-52e9-46c4-a551-acd3e827e00b' User entered '97.3'	System	16 Oct 2020 00:16:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2b876256-52e9-46c4-a551-acd3e827e00b'	System	16 Oct 2020 00:16:05
User entered 'No (N)'	System	16 Oct 2020 00:16:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:16:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2b876256-52e9-46c4-a551-acd3e827e00b'	System	16 Oct 2020 00:16:05
User entered '15 Oct 2020 19:16'	System	16 Oct 2020 00:16:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 4'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:19:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b7ea2ca-c8a1-43b7-8775-31aaa180478e' User entered 'Yes (Y)'	System	17 Oct 2020 01:21:12
	System	17 Oct 2020 01:21:12

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:20:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b7ea2ca-c8a1-43b7-8775-31aaa180478e' User entered '97.4'	System	17 Oct 2020 01:21:12

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:20:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b7ea2ca-c8a1-43b7-8775-31aaa180478e'	System	17 Oct 2020 01:21:12
User entered 'No (N)'	System	17 Oct 2020 01:21:12

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:20:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b7ea2ca-c8a1-43b7-8775-31aaa180478e' User entered '16 Oct 2020 20:20'	System	17 Oct 2020 01:21:12
	System	17 Oct 2020 01:21:12

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 5'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:39:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '047475bc-1917-4251-8847-0aa0bb0c7f74'	System	18 Oct 2020 00:41:09
User entered 'Yes (Y)'	System	18 Oct 2020 00:41:09

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:41:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '047475bc-1917-4251-8847-0aa0bb0c7f74'	System	18 Oct 2020 00:41:09
User entered '97.8'	System	18 Oct 2020 00:41:09

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:41:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '047475bc-1917-4251-8847-0aa0bb0c7f74'	System	18 Oct 2020 00:41:09
User entered 'No (N)'	System	18 Oct 2020 00:41:09

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:41:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '047475bc-1917-4251-8847-0aa0bb0c7f74'	System	18 Oct 2020 00:41:09
User entered '17 Oct 2020 19:41'	System	18 Oct 2020 00:41:09

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 6'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '454c7c1b-7601-4566-bce6-4fa771662573' User entered 'Yes (Y)'	System	19 Oct 2020 00:46:56
	System	19 Oct 2020 00:46:56

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '454c7c1b-7601-4566-bce6-4fa771662573'	System	19 Oct 2020 00:46:56
User entered '98.2'	System	19 Oct 2020 00:46:56

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '454c7c1b-7601-4566-bce6-4fa771662573'	System	19 Oct 2020 00:46:56
User entered 'No (N)'	System	19 Oct 2020 00:46:56

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:54', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '454c7c1b-7601-4566-bce6-4fa771662573'	System	19 Oct 2020 00:46:56
User entered '18 Oct 2020 19:46'	System	19 Oct 2020 00:46:56

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 7'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:42', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5e0b9fd7-c7c7-45ba-aa61-e4174964e125'	System	20 Oct 2020 01:56:55
User entered 'Yes (Y)'	System	20 Oct 2020 01:56:55

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5e0b9fd7-c7c7-45ba-aa61-e4174964e125'	System	20 Oct 2020 01:56:55
User entered '98.2'	System	20 Oct 2020 01:56:55

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5e0b9fd7-c7c7-45ba-aa61-e4174964e125'	System	20 Oct 2020 01:56:55
User entered 'No (N)'	System	20 Oct 2020 01:56:55

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5e0b9fd7-c7c7-45ba-aa61-e4174964e125'	System	20 Oct 2020 01:56:55
User entered '19 Oct 2020 20:56'	System	20 Oct 2020 01:56:55

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde' User entered 'None (1)'	System	13 Oct 2020 16:48:11
	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:50', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde'	System	13 Oct 2020 16:48:11
User entered 'No (N)'	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde'	System	13 Oct 2020 16:48:11
User entered 'No (N)'	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde' User entered 'None (1)'	System	13 Oct 2020 16:48:11
	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde'	System	13 Oct 2020 16:48:11
User entered '13 Oct 2020 11:48'	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:34'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:04'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165'	System	14 Oct 2020 00:37:14
User entered 'None (1)'	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165'	System	14 Oct 2020 00:37:14
User entered 'No (N)'	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:37:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165'	System	14 Oct 2020 00:37:14
User entered 'No (N)'	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:37:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165'	System	14 Oct 2020 00:37:14
User entered 'None (1)'	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:37:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165' User entered '13 Oct 2020 19:37'	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 2'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fedf' User entered 'None (1)'	System	15 Oct 2020 00:40:18
	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefd'	System	15 Oct 2020 00:40:18
User entered 'No (N)'	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:40:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefb' User entered 'No (N)'	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:40:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefd' User entered 'None (1)'	System	15 Oct 2020 00:40:18
	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:40:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefd' User entered '14 Oct 2020 19:40'	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 3'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad'	System	16 Oct 2020 00:15:38
User entered 'None (1)'	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:05', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad'	System	16 Oct 2020 00:15:38
User entered 'No (N)'	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad'	System	16 Oct 2020 00:15:38
User entered 'No (N)'	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad'	System	16 Oct 2020 00:15:38
User entered 'None (1)'	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:35', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad'	System	16 Oct 2020 00:15:38
User entered '15 Oct 2020 19:15'	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 4'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered 'None (1)'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered 'No (N)'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered 'No (N)'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:19:03', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered 'None (1)'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:19:05', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered '16 Oct 2020 20:19'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 5'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d'	System	18 Oct 2020 00:39:18
User entered 'None (1)'	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d'	System	18 Oct 2020 00:39:18
User entered 'No (N)'	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d'	System	18 Oct 2020 00:39:18
User entered 'No (N)'	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:39:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d' User entered 'None (1)'	System	18 Oct 2020 00:39:18
	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:39:14', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d'	System	18 Oct 2020 00:39:18
User entered '17 Oct 2020 19:39'	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 6'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb'	System	19 Oct 2020 00:46:13
User entered 'None (1)'	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb'	System	19 Oct 2020 00:46:13
User entered 'No (N)'	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb' User entered 'No (N)'	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:08', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb' User entered 'None (1)'	System	19 Oct 2020 00:46:13
	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb'	System	19 Oct 2020 00:46:13
User entered '18 Oct 2020 19:46'	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 7'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31'	System	20 Oct 2020 01:56:39
User entered 'None (1)'	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:18', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31'	System	20 Oct 2020 01:56:39
User entered 'No (N)'	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:23', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31'	System	20 Oct 2020 01:56:39
User entered 'No (N)'	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31'	System	20 Oct 2020 01:56:39
User entered 'None (1)'	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31'	System	20 Oct 2020 01:56:39
User entered '19 Oct 2020 20:56'	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:30', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870'	System	13 Oct 2020 16:49:07
User entered 'None (0)'	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870'	System	13 Oct 2020 16:49:07
User entered 'None (0)'	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870'	System	13 Oct 2020 16:49:07
User entered 'None (0)'	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870'	System	13 Oct 2020 16:49:07
User entered 'None (0)'	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870'	System	13 Oct 2020 16:49:07
User entered 'None (0)'	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870'	System	13 Oct 2020 16:49:07
User entered 'None (0)'	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870'	System	13 Oct 2020 16:49:07
User entered 'No (N)'	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:49:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870'	System	13 Oct 2020 16:49:07
User entered '13 Oct 2020 11:49'	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:34'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:04'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:11', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0'	System	14 Oct 2020 00:36:50
User entered 'None (0)'	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-eb0cd0ae2d0'	System	14 Oct 2020 00:36:50
User entered 'None (0)'	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0'	System	14 Oct 2020 00:36:50
User entered 'None (0)'	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:30', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0'	System	14 Oct 2020 00:36:50
User entered 'None (0)'	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0'	System	14 Oct 2020 00:36:50
User entered 'None (0)'	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0'	System	14 Oct 2020 00:36:50
User entered 'None (0)'	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0'	System	14 Oct 2020 00:36:50
User entered 'No (N)'	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0'	System	14 Oct 2020 00:36:50
User entered '13 Oct 2020 19:36'	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 2'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050'	System	15 Oct 2020 00:39:56
User entered 'None (0)'	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:32', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050'	System	15 Oct 2020 00:39:56
User entered 'None (0)'	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050'	System	15 Oct 2020 00:39:56
User entered 'None (0)'	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050'	System	15 Oct 2020 00:39:56
User entered 'None (0)'	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:42', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050'	System	15 Oct 2020 00:39:56
User entered 'None (0)'	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050'	System	15 Oct 2020 00:39:56
User entered 'None (0)'	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050'	System	15 Oct 2020 00:39:56
User entered 'No (N)'	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050'	System	15 Oct 2020 00:39:56
User entered '14 Oct 2020 19:39'	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 3'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'None (0)'	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859'	System	16 Oct 2020 00:15:03
User entered 'None (0)'	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:44', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859'	System	16 Oct 2020 00:15:03
User entered 'None (0)'	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859'	System	16 Oct 2020 00:15:03
User entered 'None (0)'	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859'	System	16 Oct 2020 00:15:03
User entered 'None (0)'	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'None (0)'	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859'	System	16 Oct 2020 00:15:03
User entered 'No (N)'	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered '15 Oct 2020 19:14'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 4'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441'	System	17 Oct 2020 01:18:37
User entered 'None (0)'	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:09', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441'	System	17 Oct 2020 01:18:37
User entered 'None (0)'	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:11', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441'	System	17 Oct 2020 01:18:37
User entered 'None (0)'	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:14', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered 'None (0)'	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:16', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441'	System	17 Oct 2020 01:18:37
User entered 'None (0)'	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:23', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441'	System	17 Oct 2020 01:18:37
User entered 'None (0)'	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:30', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441'	System	17 Oct 2020 01:18:37
User entered 'No (N)'	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:32', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441'	System	17 Oct 2020 01:18:37
User entered '16 Oct 2020 20:18'	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 5'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:44', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:50', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'No (N)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered '17 Oct 2020 19:38'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 6'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70'	System	19 Oct 2020 00:45:48
User entered 'None (0)'	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70'	System	19 Oct 2020 00:45:48
User entered 'None (0)'	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:31', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70'	System	19 Oct 2020 00:45:48
User entered 'None (0)'	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:35', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70'	System	19 Oct 2020 00:45:48
User entered 'None (0)'	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70'	System	19 Oct 2020 00:45:48
User entered 'None (0)'	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70'	System	19 Oct 2020 00:45:48
User entered 'None (0)'	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70'	System	19 Oct 2020 00:45:48
User entered 'No (N)'	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70'	System	19 Oct 2020 00:45:48
User entered '18 Oct 2020 19:45'	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 7'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:55:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd'	System	20 Oct 2020 01:56:13
User entered 'None (0)'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:55:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd'	System	20 Oct 2020 01:56:13
User entered 'None (0)'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:55:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd'	System	20 Oct 2020 01:56:13
User entered 'None (0)'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:55:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered 'None (0)'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd'	System	20 Oct 2020 01:56:13
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered 'None (0)'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd'	System	20 Oct 2020 01:56:13
User entered 'No (N)'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered '19 Oct 2020 20:56'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 01:56:13
User entered 'Day 8'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:56:40

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-20T13:44:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e4cc8f67-caa1-42a4-b750-16b82f2953a5'	System	20 Oct 2020 18:45:07
User entered 'None (0)'	System	20 Oct 2020 18:45:07

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-20T13:45:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e4cc8f67-caa1-42a4-b750-16b82f2953a5' User entered '20 Oct 2020 13:45'	System	20 Oct 2020 18:45:07
	System	20 Oct 2020 18:45:07

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Oct 2020 01:56:13
User entered 'Day 8'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:56:40

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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-20T13:44:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '96154570-9b23-4ec9-a74b-6b1b91fea85f'	System	20 Oct 2020 18:44:55
User entered 'No (N)'	System	20 Oct 2020 18:44:55

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:56:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-20T13:44:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '96154570-9b23-4ec9-a74b-6b1b91fea85f' User entered '20 Oct 2020 13:44'	System	20 Oct 2020 18:44:55
	System	20 Oct 2020 18:44:55

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:56:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:56:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 01:56:13

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:32:34

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	(b) (4), (b) (6)	21 Oct 2020 19:32:34

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Oct 2020 19:32:34

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:32:34

US3312629

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:32:40

US3312629

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 19:32:40

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 17:18:57

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 17:18:57

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Oct 2020 17:18:57

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 17:18:57

US3312629

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 17:19:05

US3312629

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 17:19:05

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 15:33:44

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '03 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 15:33:44

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Nov 2020 15:33:44

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 15:33:44

US3312629

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 15:33:28

US3312629

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 15:33:28

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:50:23

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:50:23

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Nov 2020 20:50:23

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	19 Nov 2020 20:50:23

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '10:45'	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 10:45'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '121'	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:50:52

US3312629

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:50:52

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:51:04

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:51:04

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:29'	(b) (4), (b) (6)	19 Nov 2020 20:51:04

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 11:29'	System	19 Nov 2020 20:51:04

US3312629

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:51:09

US3312629

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 20:51:09

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 64'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-11T04:28:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '14dd6fc3-97c9-43ad-a8bc-b7076896c848'	System	11 Nov 2020 10:28:27
User entered 'No (N)'	System	11 Nov 2020 10:28:27

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-11T04:27:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '14dd6fc3-97c9-43ad-a8bc-b7076896c848'	System	11 Nov 2020 10:28:27
User entered 'No (N)'	System	11 Nov 2020 10:28:27

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-11T04:28:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '14dd6fc3-97c9-43ad-a8bc-b7076896c848' User entered '11 Nov 2020 04:28:25'	System	11 Nov 2020 10:28:27
	System	11 Nov 2020 10:28:27

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 71'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-18T04:52:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '42eb7e57-decd-40a9-94ff-92e1b0b5aec0' User entered 'No (N)'	System	18 Nov 2020 10:53:10
	System	18 Nov 2020 10:53:10

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-18T04:53:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '42eb7e57-decd-40a9-94ff-92e1b0b5aec0' User entered 'No (N)'	System	18 Nov 2020 10:53:10
	System	18 Nov 2020 10:53:10

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-18T04:53:08', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '42eb7e57-decd-40a9-94ff-92e1b0b5aec0' User entered '18 Nov 2020 04:53:08'	System	18 Nov 2020 10:53:10
	System	18 Nov 2020 10:53:10

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 18:30:46
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349'	System	22 Nov 2020 20:53:24
User entered 'Yes (Y)'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349'	System	22 Nov 2020 20:53:24
User entered 'No (N)'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered 'Yes (Y)'	System	22 Nov 2020 20:53:24
	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24
	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '1'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24
	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '1'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '1'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24
	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349'	System	22 Nov 2020 20:53:24
User entered '1'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Please 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:53:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349'	System	22 Nov 2020 20:53:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:53:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349'	System	22 Nov 2020 20:53:24
User entered 'No (N)'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:53:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '22 Nov 2020 14:53:12'	System	22 Nov 2020 20:53:24
	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:42:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:40

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:40

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '09:53'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:40

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 09:53'	System	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:40

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Safety Call (Safety Call)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:40

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Date](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:56:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Date](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:56:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Date](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.8' F	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:56:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '11:33'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:33'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Height (xxx.x)

Audit	User	Time (GMT)
User entered '65' in	Karol Moore (b) (4)	23 Nov 2020 20:24:23
DataPoint set to visible.	(b) (4) System	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '217.8' lb	Karol Moore (b) (4)	23 Nov 2020 20:24:23
DataPoint set to visible.	(b) (4) System	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '16'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:32

US3312629

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:32

US3312629

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:56:40

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:41

US3312629

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:56:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:41

US3312629

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:56:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:46:09

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:33
User entered 'USA-US300-2020-mRNA-1273-P301000012'	System	10 Nov 2020 22:11:29
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 22:11:29

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 18:54:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 18:54:35
Data point term sent to Coder	System	09 Nov 2020 18:53:40
User entered 'small bowel obstruction'	(b) (4), (b) (6) (b) (4)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:53:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:53:32
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Severity](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 18:53:28
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'Grade 3 correct as entered. Per source, Grade 4 is not an option.' (Site from Safety).	Karol Moore (b) (4)	20 Nov 2020 16:01:18
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4)	19 Nov 2020 13:50:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[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).	(b) (4), (b) (6)	13 Nov 2020 13:54:13
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 with 'subject still currently admitted' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 18:53:24
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	09 Nov 2020 18:53:00
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:53:32
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:53:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:49:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:49:44
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)	19 Nov 2020 13:49:05
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)	19 Nov 2020 13:48:53

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PER PHONE CALL with subject 11/09/2020 53 Y/O WOMAN WITH H/O DIVERTICULOSIS AND PARTIAL COLECTOMY, SLEEVE GASTRECTOMY, INCISIONAL HERNIAS, & HIATAL HERNIA WHO DEVELOPED ABDOMINAL PAIN ON 06NOV2020 THAT RESULTED IN ER VISIT. SMALL BOWEL OBSTRUCTION WAS DIAGNOSED; EVAL INCLUDED CT SCAN AND XRAYS.TREATED WITH IV FENTANYL AND TORADOL AND NPO WITHOUT NG Tube,HER DIET WAS ADVANCED TO CLEAR LIQUIDS BY 08NOV2020. HER CARE TEAM HOPES TO ADVANCE TO FULL LIQUIDS TODAY, 09NOV2020. SUBJECT'S PAIN WAS WELL CONTROLLED AND SHE WAS IN NO DISTRESS AT TIME OF PHONE CONTACT TODAY. SBO BELIEVED TO BE RELATED TO ADHESIONS RELATED TO PREVIOUS PROCEDURES. THIS IS AN SAE OF SBO, NR TO IP. UPDATE 11NOV2020: SUBJECT DISCHARGED FROM HOSPITAL WITHOUT ADDITIONAL INTERVENTION, HAS HAD BOWEL MOVEMENTS AND WITHOUT PAIN. MR PENDING.Update:Medical records reviewed.Subject was admitted 06Nov2020 with partial small bowel obstruction related to adhesions from history of multiple abdominal surgeries.On date of admission developed epigastric abdominal pain at approximately 12:45 pm that progressively worsened to 8 out of 10 severity over hours.Self induced emesis (non-bloody) did not relieve pain.She went to local ER where care was initiated but transferred to another same day.Overall work-up revealed negative Covid test 06Nov2020,dilated loops of bowel without evidence of pneumatosis or ischemia and consistent with partial small bowel obstruction on imaging, neutrophil elevation to 9000/microL without signs of infection consistent with stress and pain related elevation, abdominal pain that resolved with iv pain meds, and lactate level of 3.14 that decreased to 1.3	(b) (4), (b) (6)	18 Nov 2020 23:39:17

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Narrative](#)

Audit	User	Time (GMT)
with iv fluids. Treatment was conservative with npo, then advancement of diet. On day of DC 10Nov2020 subject looked and felt well, had 2 normal bowel movements, and a mild hypokalemia of 3.3 that was corrected. AE resolved' reason for change: Data Entry Error		
User entered 'SUBJECT IS HISTORIAN PER PHONE CALL 11/09/2020 53 Y/O WOMAN WITH H/O DIVERTICULOSIS AND PARTIAL COLECTOMY, SLEEVE GASTRECTOMY, INCISIONAL HERNIAS, AND HIATAL HERNIA WHO DEVELOPED ABDOMINAL PAIN ON 06NOV2020 THAT RESULTED IN ER VISIT. SMALL BOWEL OBSTRUCTION (SBO) WAS DIAGNOSED; EVAL INCLUDED CT SCAN AND XRAYs. SUBJECT WAS TREATED WITH IV FENTANYL AND TORADOL AND NPO WITHOUT NASOGASTRIC TUBE. HER DIET WAS ADVANCED TO CLEAR LIQUIDS BY 08NOV2020. HER CARE TEAM HOPES TO ADVANCE TO FULL LIQUIDS TODAY, 09NOV2020. SUBJECT'S PAIN WAS WELL CONTROLLED AND SHE WAS IN NO DISTRESS AT TIME OF PHONE CONTACT TODAY. SBO BELIEVED TO BE RELATED TO ADHESIONS RELATED TO PREVIOUS PROCEDURES. THIS IS AN SAE OF SBO, NR TO IP. update 11Nov2020: subject discharged from hospital without additional intervention, has had bowel movements and without pain. medical records pending' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:54:42

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject is historian per phone call 11/09/2020 53 y/o woman with h/o diverticulosis and partial colectomy, sleeve gastrectomy, incisional hernias, and hiatal hernia who developed abdominal pain on 06Nov2020 that resulted in ER visit. Small bowel obstruction (SBO) was diagnosed; eval included CT scan and Xrays. Subject was treated with iv fentanyl and toradol and NPO without nasogastric tube. Her diet was advanced to clear liquids by 08Nov2020. Her care team hopes to advance to full liquids today, 09Nov2020. Subject's pain was well controlled and she was in no distress at time of phone contact today. SBO believed to be related to adhesions related to previous procedures. This is an SAE of SBO, NR to IP.'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Epicondylitis, LLT: Tennis elbow - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:10:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:10:50
Data point term sent to Coder	System	19 Nov 2020 20:58:21
User entered 'LEFT TENNIS ELBOW (lateral epicondylitis)'	(b) (4), (b) (6) (b) (4)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 20:57:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:56:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:07:27

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[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: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:10:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:10:26
Data point term sent to Coder	System	05 Oct 2020 17:09:16
User entered 'atorvastatin'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypercholesterolemia'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '80'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:10:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:10:26
Data point term sent to Coder	System	05 Oct 2020 17:09:16
User entered 'escitalopram'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'anxiety'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:58:22
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 04:58:22
Data point term sent to Coder	System	05 Oct 2020 17:10:18
User entered 'pantoprazole'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'current hiatal hernia'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[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)	05 Oct 2020 17:13:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:13:28
Data point term sent to Coder	System	05 Oct 2020 17:11:22
User entered 'montelukast'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal allergies'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'nightly'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 12:44:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 12:44:14
Data point term sent to Coder	System	05 Oct 2020 17:12:23
User entered 'amitriptyline'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'migraines'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'nightly'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Feb 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:15:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:15:20
Data point term sent to Coder	System	05 Oct 2020 17:14:27
User entered 'famotidine'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'acid reflux'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:15:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:15:20
Data point term sent to Coder	System	05 Oct 2020 17:14:27
User entered 'loratidine'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal allergies'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Oct 2020 17:16:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Oct 2020 17:16:23
Data point term sent to Coder	System	05 Oct 2020 17:15:31
User entered 'fluticasone'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'seasonal allergies'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 27.5 MCG, 50 MCG, etc) instead of sprays count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:14:16
User entered '1'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'spray'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Nasal (NASAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[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)	05 Oct 2020 17:16:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:16:24
Data point term sent to Coder	System	05 Oct 2020 17:15:31
User entered 'aspirin'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:14:39
User entered 'general health maintenance'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:17:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:17:27
Data point term sent to Coder	System	05 Oct 2020 17:16:33
User entered 'sumatriptan'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'migraines'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Feb 2020'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:17:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:17:28
Data point term sent to Coder	System	05 Oct 2020 17:16:33
User entered 'ibuprofen'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'migraines'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '800'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[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: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:18:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:18:32
Data point term sent to Coder	System	05 Oct 2020 17:17:34
User entered 'acetaminophen'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'migraines'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: OTHER ANTI OBESITY DRUGS, PRODUCT: LIRAGLUTIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 19:46:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 19:46:34
Data point term sent to Coder	System	06 Oct 2020 19:45:05
User entered 'liraglutide'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'obesity'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '3'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Jun 2020'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH condition has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:15:19
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 04:15:42
Data point term sent to Coder	System	09 Nov 2020 18:54:43
User entered 'toradol'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'small bowel obstruction'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 18:55:33
User entered '50'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 18:55:33
User entered 'ug (ug)'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:58:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:58:03
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:56:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:56:43
Data point term sent to Coder	System	09 Nov 2020 18:55:44
User entered 'fentanyl'	(b) (4), (b) (6) (b) (4)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 18:55:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 18:55:10
User entered 'small bowel obstruction' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 18:55:10
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 18:54:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:57:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:57:50
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[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)	20 Nov 2020 03:30:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:30:53
Data point term sent to Coder	System	19 Nov 2020 20:53:16
User entered 'SEASONAL INFLUENZA VACCINE'	(b) (4), (b) (6) (b) (4)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'SEASONAL INFLUNEZA PROPHYLAXIS'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

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

Audit	User	Time (GMT)
User entered '08 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 10:15:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 10:15:10
Data point term sent to Coder	System	19 Nov 2020 20:55:18
User entered 'CORTISONE'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT TENNIS ELBOW'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'INJECTION'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'intraarticular'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:53:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 07:53:19
Data point term sent to Coder	System	19 Nov 2020 20:56:19
User entered 'IBUPROFEN'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT TENNIS ELBOW'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '800'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:56:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 20:56:05

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'USA-US300-2020-MRNA-1273-P301000012'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Carlos'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Fierro'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '16300 College Blvd'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Shawnee'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'KS'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '66219'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'US'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:58:51
User entered '2'	System	12 Nov 2020 18:36:52
User entered '1'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'USA-US300-2020-MRNA-1273-P301000012'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Carlos'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Fierro'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '16300 College Blvd'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Shawnee'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'KS'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '66219'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'US'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:58:51
User entered '2'	System	12 Nov 2020 18:36:52
User entered '1'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
User entered '10/Nov/2020 22:11'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:40

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'USA-US300-2020-MRNA-1273-P301000012'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Carlos'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Fierro'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '16300 College Blvd'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Shawnee'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'KS'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '66219'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'US'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:58:51
User entered '2'	System	12 Nov 2020 18:36:52
User entered '1'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
User entered '12/Nov/2020 13:36'	System	12 Nov 2020 18:36:52

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:40

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 18:36:52

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'USA-US300-2020-MRNA-1273-P301000012'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Carlos'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Fierro'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '16300 College Blvd'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Shawnee'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'KS'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '66219'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'US'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:58:51
User entered '2'	System	12 Nov 2020 18:36:52
User entered '1'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:56:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
User entered '19/Nov/2020 13:58'	System	19 Nov 2020 18:58:51

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:56:40

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:25:35
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 18:58:51